

# **ANNUAL REPORT ON THE SINGLE INTEGRATED MULTIANNUAL NATIONAL CONTROL PLAN: AHWD 2019**

## **VETERINARY REGULATION DIRECTORATE**

Within the Animal Health and Welfare Department (AHWD) there are two Directorates:

- (a) the Veterinary Regulation Directorate (VRD) and
- (b) the Animal Welfare and Promotion Service Directorate (AWPSD).

The AWPSD directorate deals mostly with issues related to pets. This directorate did not form part of the MANCP and its Annual Report. A memo has been signed between VRD and AWPSD to clarify their respective responsibilities.

With respect to the VRD, this directorate comprises a number of units as follows:

- (a) the Animal Health and Welfare Unit (AHWU),
- (b) the Policy and Enforcement Unit (PEU),
- (c) the Trade Unit (TU) and
- (d) the Safety of the Food Chain Unit (SFCU).

The AHWU is responsible for animal health and animal welfare and for the latter area, it is also responsible for policy and specific controls on animal welfare related legislation. The PEU coordinates the VRD's position on different EU legislation and policies, the enactment of draft legislation as well as requests for enforcement action originating from the various Units, also following judicial cases in court proceedings if necessary. The Trade Unit is responsible for controls on goods and animals coming to Malta including the Border Inspection Posts (BIPs). The SFCU is responsible for veterinary public health (including animal by-products, ABP).

Veterinary medicines, implementation of residues plan and feeding stuffs fall under the National Veterinary Laboratory (NVL) in line with the Veterinary Services Act (Cap. 437); the Laboratory implements also analysis for VRD in line with various National and EU legislation.

The VRD units report to the Director VRD who also serves as the Chief Veterinary Officer (CVO). Coordination of EU and national legislation falls directly under the responsibility of the CVO. Legal powers are provided in the Food Safety Act (CAP.449), the Veterinary Services Act (CAP.437) and Animal Welfare Act (CAP.439). The post of Director General of the AHWD has been filled from November 2014; the Head of the NVL reports administratively to the Director General AHWD.

To note that a separate government veterinary service operates on the island of Gozo and falls administratively under the Ministry for Gozo but receives technical instructions from the VRD.

Control activities in the area of animal health, animal welfare and food of animal origin, animal by-products, veterinary medicines, and animal feeding stuffs takes place through inspections; audits; sampling; monitoring and analyses. For this reason, VRD prepares annual plans and sets the inspection frequencies for inspectors. Controls of animal health and zoonoses are performed mainly via monitoring and supplemented by sampling. Monitoring is based on annual disease control programmes which take into account past sampling results and records.

**Part 1**

**Official controls performed by the Member State as provided for in Article 3 of Regulation (EC) No 882/2004 and national control plans — Section 9.1;**

**(A) ANIMAL HEALTH AND WELFARE UNIT**

This unit made several inspections related to animal welfare on various animals mainly pigs, laying hens, broiler chickens, zoos and their animals, private collections of dangerous animals and pet shops.

Completed laws	Internal procedures completed	Kwerele started	Written warnings	Consultations with the planning authority
1	3	5	4	25

Farm insp.	Reports on animal welfare from the public	Boarding/ Kennel insp.	Zoo or illegal zoo insp.	Pet shops insp.	Sanctuary insp.

38	14	3	31	58	10
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Insp= Inspections

## ANIMAL HEALTH UNIT

### Contingency planning.

**National Contingency plan** for animal diseases is regularly updated and available at VRD.

**Risk assessment.** In order to prioritize prevention and preparedness and in order to and identify better control measures to limit the possibility of introduction and spread of animal diseases, a risk assessment for highly contagious diseases was carried out during 2018 and regularly revised according to the epidemiological situation of the different diseases considered.

Risk was defined as being composed of two contributing components:

- the likelihood (probability) of the hazard causing the unwanted outcome,
- a measure of the impact (consequences) of the unwanted outcome

Malta is part of the REMESA (Animal health network of the Mediterranean countries). Regular meetings are organized to share risk information between the member countries of North Africa and Southern Europe.

A senior veterinary officer of the Animal Health Unit (Veterinary Regulation Directorate) regularly collaborates with FAO/EuFMD within a programme aimed at improving control of FMD in the North Africa, Middle East and Turkey. The regular participation to international fora on animal health allows to collect risk information useful for keeping a regular monitoring of the animal disease threats in the neighbouring countries.

## TRAINING AND AWARENESS

25 courses were organised during 2019 as per table below:

	Course Title
1.	Bird of Prey Awareness workshop

2.	Prudent use of Antimicrobials in animals (AMR)
3.	Biosecurity Measures on Poultry, Swine and Ruminant farms
4.	Prevention and Control of Antimicrobial Resistance (AMR) in the context of an overall 'One Health' Approach to prevention and control of infections and reducing Antimicrobial Resistance
5.	Implementation of union rules in relation to microbiological criteria and on the monitoring and control of zoonosis and zoonotic agents.
6.	Auditing General Hygiene Requirements and Control Procedures based on the HACCP principles developed by food business operators
7.	Animal Welfare during Transportation Advance level.
8.	Putting Vaccination into Practice
9.	Training on Emergency Preparedness for transmissible animal diseases in the EU-ASF and AI
10.	Prevention and Control of Antimicrobial Resistance (AMR) in the context of an overall 'One Health' Approach to prevention and control of infections and reducing Antimicrobial Resistance-BTSF internal dissemination
11.	Prudent use of Antimicrobials in animals (AMR)-BTSF internal dissemination
12.	Refresher training for OV on emergency roster
13.	Animal Welfare during Transportation Advanced -BTSF internal dissemination
14.	Implementation of union rules in relation to microbiological criteria and on the monitoring and control of zoonosis and zoonotic agents-BTSF internal dissemination.
15.	HACCP Principles and Audit Techniques-BTSF internal dissemination

16.	Simulation exercise on the contamination of milk and feed with an Aflatoxin
17.	Control of commercial and non-commercial movements of dogs and cats-BTSF internal dissemination
18.	Training on the use of the Common Health Entry Document for animals (CHED-A) and products of animal origin, germinal products and animal by-products (CHED-P) in TRACES-NT-internal dissemination
19.	Food Hygiene at Primary Production” – PP Session 4 Land Animals-BTSF internal dissemination
20.	Milk Sampling and filling up of relevant documents
21.	Assisting the OV in red meat slaughterhouses
22.	Basic Procurement Procedures
23.	General inspections on farm
24.	International Bees Symposium
25.	ERA requirements training for OPM joint inspections on farms

## **PROPHYLAXIS SECTION**

The Prophylaxis Section within the VRD is responsible for the ruminant disease surveillance with particular focus on the Tuberculosis, Brucellosis and Enzootic Bovine Leucosis (EBL) eradication schemes.

Besides the collection of samples and performing the skin test for tuberculosis control, the section is also responsible for the census inspection and for tagging and re-tagging of bovines and small ruminants. These activities are carried out on dairy and non-dairy ruminant farms in accordance with EU legislation.

### **Bovine tuberculosis**

Controls are carried out in all dairy farms through the intradermal comparative skin test. All slaughtered animals are also inspected prior to slaughter and carcasses are then visibly inspected on the slaughter line for any granulomatous lesions within lymph nodes suggestive of bovine tuberculosis. All dairy farms were considered officially TB free at the end of 2019 and were visited at least once a year or more depending on risk assessment.

15,348 testes on bovines were performed on bovines on dairy farms in the Maltese Islands.

### **Bovine and ovi-caprine Brucellosis**

Bovine (dairy farms) and ovi-caprine farms are regularly controlled by carrying out serological tests and bulk milk tests in bovine dairy herds.

All dairy farms achieved the officially free status and are sampled at least once a year on farm. Blood samples are also collected from all the slaughtered animals.

A total of 14,314 testes for brucellosis have been performed on bovines in dairy farms, during 2019.

*Table 1: Brucellosis and Tuberculosis testing on dairy farms in 2019 (Malta and Gozo)*

<b>Tuberculosis</b>	<b>Brucellosis dairy farm</b>
Bovines	Bovines
15348	14314

### **Tuberculosis reactors**

All bovines were tested negative to the intradermal comparative skin test for Tuberculosis except 6 bovines that resulted positives and 6 bovines that had a doubtful reaction 2 consecutive times, for a total of 12 animals. All positive and doubtful reactors were detected in 9 farms. Confirmatory tests resulted all negative.

*Table 2: Tuberculosis reactors on dairy farms*

Species	Bovine	Caprine
Total	12	0

### **Brucella reactors**

No ruminants were tested positive to the Brucellosis in dairy farm.

*Table 3: Brucella reactors on dairy farms*

Species	Bovine	Caprine	Ovine
Total	0	0	0

During 2019 no cases of leucosis were found on dairy farms; 7736 bovines were sampled in the Maltese Islands. The results are shown in the table below.

*Table 4: Leucosis testing on dairy farms and positive cases in 2019 (Malta and Gozo)*

Malta & Gozo	Inconclusive	Negatives	Positives	Bovines Sampled
Total*	0	7736	0	7736

### **Multiannual results**

The following charts show the number of screened positives cases in the last 6 years in cattle Dairy farms in Malta and Gozo.

*Table 6: Number of Brucellosis, Tuberculosis and EBL positive cases (dairy herds)*

Year	Tuberculosis	Brucellosis	Leucosis
2019	12	0	0
2018	5	0	0
2017	6	0	1
2016	0	0	0
2015	0	0	1
2014	0	0	1

### **Non-dairy farms**

Non-dairy farms, which also include the Registered Cheeselet Producers, hold the majority of sheep and goats present on the Maltese islands. These holdings are subdivided into two categories; farms rearing only sheep and/or goats (RUM) and farms that rear also bovines (mostly bulls) for fattening and slaughter (RUM-B).

*Brucella* sampling was carried out on non-dairy farms in Malta and Gozo, as seen in the following tables. Some Tuberculosis testing was carried out on few farms that rear bovines for fattening and also on caprine if they are kept on the same premises with the bovines.

Table 7: Number of animal tested for Brucellosis and Tuberculosis in Malta and Gozo

Malta	Brucellosis non-dairy farm				Tuberculosis	
	Total Brucellosis Testing	Bovine	Caprine	Ovine	Total TB Testing	Bovine
Total	25,533	387	7348	17,798	304	304

#### **Brucella reactors**

All ovine and caprine that gave a positive reaction to the Rose Bengal Test (screening test) resulted negative in the confirmatory test.

Table 6: *Brucella* reactors on non-dairy farms.

Species	Bovine	Caprine	Ovine	Total
Positive	0	0	0	0

#### **Tuberculosis reactors**

All bovine and caprine were tested negative.

Table 7: Tuberculosis reactors on non-dairy farms.



Species	Bovine
Total	0

Table 8: Leucosis testing on non dairy farms and positive cases in 2019 (Malta and Gozo)

Malta & Gozo	Inconclusive	Negatives	Positives	Bovines Sampled
Total*	0	133	0	133

## SWINE SECTION

Swine Population					
	Farms	Heads	Sows	Boars	Growers
Malta	95	36,173	2,350	106	33,717
Gozo	9	2,986	262	9	2,715
Total	104	39,159	2,612	115	36,432

Table: Swine population in Malta and Gozo (as at 31/12/2019)

Main results for 2019:

- 51,499 piglets were registered on the NLD
- 701 imported growers were registered on the NLD
- 234 sows/sows boars were registered as breeding stock

- 12 transfer applications were received and approved, including 250 animals
- 104 farms were licensed as pig farms
- 27 licences for swine kept as pet were issued in 2019

## **ANIMAL IDENTIFICATION CONTROLS**

### **Animal Identification**

#### **1. Ruminants identification**

##### **1.1 Calf Identification Scheme**

Tagging of bovines according to the relevant EU legislation continued during the year 2019. All bovines are double ear tagged using a unique identification number which has to accompany the animal throughout its entire lifetime thus ensuring the “farm to fork” traceability concept. The farmers have to notify to the Competent Authority within 7 days from each new born, and there are 20 days to put a unique ear tag for the identification of each new calf born to be in accordance with S.L. 437.84.

All data of the animals are registered in the herd book and loaded in the Veterinary Information System for the complete identification of the animals (ear tag number, date of birth, breed, sex, ear tag number of the mother). In the herd book and in the veterinary system there is also registered all the information regarding the animal movements with their provenance and destination to ensure their complete traceability.

The total number of bovines tagged on both Dairy and Non-dairy holdings is 4,819 and is shown in table 1.1 below.

##### **1.2 Ovine and Caprine Identification Scheme**

As from July 2006 a system of tagging sheep and goats has been implemented to be in line with EU Regulation No. 21/2004 whereby sheep and goats must be identified by means of a pair of ear tags bearing the MT code and a six digit number followed by a check digit. The identification numbers were inserted into the National Livestock Database (NLD) in order to maintain traceability of these animals. The system has been maintained since 2006. When a small ruminant loses a tag this is replaced with a new tag and it is recorded in the database. The total number of new tags in 2019 were 6,908.

The number of animals tagged per month on Maltese holdings is shown in table below.

*Table 1.1: Calves, lambs and kids tagging.*

<b>2019</b>	<b>Total</b>	<b>BOVINE</b>	<b>CAPRINE</b>	<b>OVINE</b>
January	1,051	4,443	86	522
February	672	415	31	226
March	1,361	416	142	803
April	1,340	328	220	792
May	1,057	276	131	650
June	723	251	107	365
July	959	324	159	476
August	1,041	478	235	328
September	912	499	168	245
October	1,034	542	129	363
November	741	366	143	232
December	836	481	104	251
<b>Total</b>	<b>11,727</b>	<b>4,819</b>	<b>1,655</b>	<b>5,253</b>

All bovine data are registered in the herd book and loaded in the Veterinary Information System for the complete identification of the animals (era tag number, date of birth, breed, sex, ear tag number of the mother). In the herd book and in the veterinary database there are also registered all the information regarding the animal movements with their provenance and destination for their complete traceability

### 1.3 Re-tagging activity

When a bovine or a small ruminant loses one of its ear tags, it is retagged using the same ear tag number (bovine) or a new number linked to previous one (small ruminants), so as to ensure its traceability. Bovine Ear tag losses are reported by farmers to the VRD and tags bearing the same numbers are re-ordered from the supplier. The number of re-tags carried out per month on Bovine holdings is shown in the table below.

*Table 1.2: Re-tagging of animals in Malta and Gozo*

<b>2019</b>	<b>Re-Tags</b>
January	267
February	17
March	629
April	140
May	292
June	190
July	296
August	170
September	149
October	282
November	213
December	255

Total	2,900
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## 2. Population

The animal population on farms in Malta and Gozo during 2019 is as shown in the tables below.

*Table 2.1: Bovine population.*

Bovine	Total	M0	M1	M2	M3	F0	F1	F2	F3
Total	14,170	1,095	914	952	135	1,253	923	2,111	6,787

Key: M0: Male bovines under six months  
M1: Male bovines between six months and 1 year  
M2: Male bovines between one and two years  
M3: Male bovines over two years  
F0: Female bovines under six months  
F1: Female bovines between six months and 1 year  
F2: Female bovines between one and two years  
F3: Female bovines over two years

*Table 2.2: Caprine population*

Caprine	Kids	Billy Goats	Goats	Total
Total	793	321	3,593	4,707

*Table 2.3: Ovine population*

Ovine	Lambs	Rams	Ewes	Total
Total	1,134	352	9,575	11,061

## **MICROCHIPPING SECTION**

The Microchipping Section is responsible for the management and control of registration and identification of pets, mainly canines, felines and equines.

### **Canines: Issuing of licences of ownership, notification of deaths, reports of missing pets and transfer of ownership.**

The Microchipping Section issues licences of ownership of canines on blank security paper with added features and in line with Legal Notice 199 of 2011. Licences are sent to their respective owners by post. Details relates to ownership and microchipping of dogs for 2019 are as follows:

#### **Activity Year 2019:**

Licences of ownership issued – 6,397

Transfer of ownership – 2,342

Death notifications – 1,730

Reports of missing canines – 18 (reported found and returned to their respective owners: 6)

General queries by email (not including telephone calls) – 3,086

### **Felines: Transfer of ownership, notification of deaths and reports of missing pets.**

In 2019, the voluntary registration of felines in the National Livestock Database was continued following its introduction on 2018 as part of the electoral manifesto presented by the government. The procedure is done in a similar way as that of canines but is purely on a voluntary basis.

#### **Activity Year 2019:**

Transfer of ownership – 166

Death notifications – 67

Reports of missing felines – 4

General queries by email (not including telephone calls) – 277

### **Equines: Issuing of identification documents, notification of deaths and transfer of ownership.**

On request of the respective owners, the Microchipping Section records equine transfers and notification of deaths. Equine identification documents are issued by this section on request of private veterinarians and are printed on blank security paper. Their layout was developed in line with Regulation 504/2008.

**Activity Year 2019:**

Transfer of ownership – 116

Death notifications – 21

Identification documents issued – 88

General queries by email (not including telephone calls) – 157

**POULTRY AND LAGOMORPHS SECTION**

**Activity 2019**

**41** samples taken from broiler farms for the salmonella national control plan (SNCP).

**28** samples taken for the SNCP in layer farms.

**1** Salmonella re-cleaning in farm.

**77** inspections were carried out both in layers and broilers farms for the evaluation of bio-security.

**27** Layer farms were sampled for Avian flu,

**3** feed samples taken from broiler farms (National Plan)

**16** feed samples taken from layer farms (National Plan)

**177** egg samples were taken from layer farms (National Plan)

**9** Fipronil egg samples

**83** Rabbit Inspections

**13** rabbit samples taken (National Plan)

Other Inspections – **3** (Waste Serve Malta)

**BEES SECTION**

**Bees Health**

During 2019, the Bees Health Section carried out inspections on 39 apiaries and a total of 205 honeybee colonies were inspected for signs of notifiable diseases and pests. There was one case of European Foulbrood in 1 apiary. 14 honey samples were collected for the National Residues Plan (NRP).

<b>Type of inspections carried out</b>	<b>No of inspections</b>
No of apiaries inspected	39
No of honeybee colonies inspected	205
No of NRP honey samples	14

## **(B) SAFETY OF THE FOOD CHAIN UNIT**

### **1) The ABP section**

**86** transport permits have been issued in total by the section.

**37** visits to the TTF in order to check the microchip of dead horses.

**59** visits to the TTF in order to check the fallen animal's identity and take the samples for the TSE tests have been carried out.

**2** inspections have been carried out in ABP establishments.

### **2) Red Meat Slaughterhouses And Cutting Plant Section**

The Malta Public Abattoir (M001), located in Marsa, is a red meat slaughterhouse where, in 2019, animals of swine, bovine, equine, ovine and caprine species were slaughtered. In 2019, the Officers of the Section carried out, on a daily basis, the ante-mortem inspection of the animals transported to the slaughterhouse, in order to evaluate the health status and the welfare conditions of the animals, and the subsequent post-mortem inspection of the slaughtered animals to assess the fitness for human consumption. Sampling according to the plans as per mandatory requirements (TSE, Trichinella, Salmonella), to National Control Plan and sampling based on suspicion and on survey were carried out (residues of substances). The samples were collected and sent to the NVL for the necessary testing.



The following table shows all animals inspected with regard to the regular slaughter, found fit for human consumption or condemned as unfit for human consumption.

The table also shows percentages of the condemned carcasses:

<b>MT001</b>	<b>REGULAR SLAUGHTER</b>						
No of Animals	BOVINE	SWINE			OVINE	CAPRINE	EQUIDS
		Fatteners	Sows	Boars			
Inspected	2,722	48,406	754	61	5,707	1,202	1
		49,221					
Fit for HC	2,651	48,277	735	59	5,600	1,182	1
		49,071					
Dead at lairage	0	1	0	0	12	3	0
Putdown	0	0	0	0	1	0	0
Condemned	71	128	19	2	94	17	0
		149					
% Condemned + Putdown	2.61%	0.30%			1.67%	1.42%	0%

*Table 1: post-mortem inspection results at the slaughterhouse in Malta as per REGULAR slaughter.*

The Gozo Civil Abattoir (M002), located in Xewkija, is a red meat slaughterhouse that where, during 2019, swine, bovine, ovine and caprine animals were slaughtered.

The following table shows all animal inspected at Gozo Civil Abattoir, found fit for human consumption or condemned as unfit for human consumption:

MT002	REGULAR SLAUGHTER						
	BOVINE	SWINE			OVINE	CAPRINE	EQUIDS
Fatteners		Sows	Boars				
No of Animals							
Inspected	1,085	2,891	23	3	727	238	0
		2,917					
Fit for HC	1,052	2,878	22	3	711	236	0
		2,903					
Dead at lairage	0	0	0	0	0	0	0
Putdown	0	0	0	0	0	0	0
Condemned	33	13	1	0	16	2	0
		14					
% Condemned + Putdown	3.04%	0.48%			2.20%	0.84%	0%

Table 2: post-mortem inspection results at the slaughterhouse in Gozo.

## Animal welfare measures

The emergency service, developed in 2012, continues to be carried out in Malta and Gozo in order to improve general welfare issues, to improve the passive surveillance on animal diseases and limit the possible spread of dangerous pathogens. Animals unfit for transport are visited (ante-mortem inspection) and slaughtered on-farm and then transported to the Marsa Abattoir or to the Gozo Abattoir for further slaughter operations and post-mortem inspection.

The following table shows all animals which have been slaughtered on-farm and then, after the further post-mortem inspection of the carcasses at the Malta and Gozo Public Abattoirs, deemed fit for human consumption or condemned as unfit for human consumption:

	<b>EMERGENCY SLAUGHTER</b>									
No of Animals	BOVINE				SWINE			OVINE	CAPRINE	EQUIDS
	M<48m	F<48m	M>48m	F>48m	Fatteners	Sows	Boars			
Inspected	13 +7	43 +11	0 +0	38 +12	7 +0	14 +0	0 +0	13 +0	2 +0	0
	94+30=124				21+0 = 21			13	2	0
HC	13 +7	38 +11	0 +0	27 +11	6 +0	13 +0	0 +0	12	2	0
	78+29=107				19+0 = 19					
NHC	0 +0	5 +0	0 +0	11 +1	1 +0	1 +0	0 +0	1	0	0
	16+1=17				2+ 0= 2					
% Condemned	13.71%				9.52%			7.69%	0%	0

*Table 3: post-mortem inspection results at the slaughterhouse in Malta and Gozo after Emergency on-farm slaughter.*

At the Malta and Gozo slaughterhouses, some animals were deemed not fit for slaughter and human consumption at ante-mortem inspection: 1 ovine was put down humanely and sent for incineration without going through the slaughter process.

### **Audits and enforcements**

The enforcement actions took the form of Corrective Action Requests (CAR), as per internal SOP Ref No: SOP/SFC/001/2011. With regard to the Marsa Public Abattoir, 1 CAR was issued due to non-compliances found.

An inspection was conducted during 2019 at the Cutting Plant annexed to the Marsa Public Abattoir. 1 CAR was issued due to non-compliances found.

### **3) White Meat Slaughterhouse Section**

Within the White Meat Slaughterhouse there is a Veterinary Officer, a Senior Support Officer and 3 Veterinary Support Officers. The mentioned Officers in this Section perform the official controls in the 4 poultry slaughterhouses present in Malta and the cutting plants.

- **Summary of the main legislation addressed by official controls in 2019.**

Legislation	Subject
Regulation (EC) N.178/2003	General principles of food law
Regulation (EC) N.882/2004	Ensuring proper checks on food and animal feed
Regulation (EC) No 852/2004	Food Hygiene

Regulation (EC) No 853/2004	Hygiene rules for food of animal origin
Regulation (EC) No 854/2004	Food products of animal origin-official controls
Regulation (EC) No 2073/2004	Microbiological criteria for foodstuff
Regulation (EC) No 1099/2009	Protection of animals at the time of killing
Directive 93/119/EC	Protection of animals at the time of slaughter or killing
Regulation (EU) No 625/2017	Official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

- **Size of control file in 2019**

Poultry slaughterhouses	Number of chickens slaughtered
MPSP050	628,546
MPSP058	530,234
MPSP053	390,462
MPSP063	769,491
<b>Total</b>	<b>2,318,733</b>
Supervision domain name	Number

- **Supervision of white meat slaughterhouses**

Inspections	927
Audits	3
<b>Total</b>	<b>930</b>

- **Sampling plan:**

Sampling	Number
Total sampling	172

- The number of the chickens which arrived dead at the slaughterhouses and were discarded at the post-mortem inspection was the following:

	No. of chickens arrived dead	No. chickens discarded
Total	2679	7088

#### 4) Rabbit Slaughterhouses

The section manages the official controls carried out in the rabbit slaughterhouses present in Malta. There are 2 approved slaughterhouses in Malta, one of which is approved to slaughter its own rabbits and the other is approved to slaughter also third-party rabbits.

There are three weekly slaughters dates and official controls include ante-mortem and post-mortem inspection during each slaughter. Thirty-three samples were taken from slaughterhouses in accordance with the National Residue plan, throughout 2019, and tested for both residues and contaminants.

The most common pathologies for detention/condemnation of carcasses were subcutaneous abscesses and technical faults.

<b>North- A</b>	<b>Rabbits Slaughtered 2019</b>	<b>South- B</b>	<b>Rabbits Slaughtered 2019</b>	<b>Rabbits Slaughtered (North + South) 2019</b>
January	3,790	January	1,197	4,987
February	4,162	February	1,198	5, 360
March	3,954	March	1,200	5,154
April	5,057	April	1,499	6,556
May	4,166	May	1,197	5,363
June	3,866	June	1,197	5,063
July	4,954	July	1,499	6,453
August	3,768	August	1,197	4,965
September	3,870	September	1,499	5,369
October	3,238	October	1,099	4,337
November	3,850	November	797	4,647
December	3,154	December	1,000	4,154
<b>Total</b>	<b>47,829</b>	<b>Total</b>	<b>14,579</b>	<b>62,408</b>

Estimated Total Number of Rabbits slaughtered in 2019: 62,408

## 5) Approved Establishment Section

The Approved Establishment Section has carried out official controls on a group of establishments requiring approval, such as those producing meat products and preparations, as detailed in the table below. The official controls varied from meetings and discussions with Food Business Operators regarding their obligations under EU and national legislation, to preliminary visits on site before issuing the approval; announced or unannounced inspections, audits, follow-up visits, on-site investigations; supervision of rapid alert recalls. A risk-based approach is taken when planning inspections and audits, following an internal procedure with a score-point system.

Following discussions with a central authority (Business inspectorate Unit within OPM) in order to harmonise all inspectorate bodies under one system, work continued to set up a computerised system for data input, co-ordination of all routine inspections, and the gathering of information on behalf of different entities by the primary Inspectorate body as part of simplification measures. All data input, including verification of self-assessment Forms will be done online.

### Dairy Farms

A total of 57 dairy active premises in Malta and 32 dairy premises in Gozo were registered with the Veterinary Regulation Directorate during the year 2019.

Category of Establishment	Audits	Audits for Approval	Inspection Un/Announced	FollowUp	Generic Visit	Preliminary discussions with New Applicants	Sampling	Enforcement	Other	Total Official Controls
Cold Stores (Section 0)	13	7	32	7	10	10		6	9	94



<b>Cutting/Deboning (Section 1)</b>	10	2	6	3	5	8		1	5	<b>40</b>
<b>Poultry/Lagomorphs (Section 2)</b>	8	2	6	3	5	8		1	4	<b>37</b>
<b>Mince Meat/Meat Preps (Section 5)</b>	7	3	6	3	6	9		1	4	<b>39</b>
<b>Meat Products (Section 6)</b>	7	4	12	4	7	10		4	3	<b>51</b>
<b>Fishery Products (Section 8)</b>	12	7	11	7	5	9	4	4	10	<b>69</b>
<b>Exclusive Re-Wrapping/Re-Packing</b>	18	6	18	8	8	9		4	5	<b>76</b>
<b>Eggs and egg products (Section 10)</b>		2	2		4	2			2	<b>12</b>
<b>Other</b>			14					2	84	<b>100</b>
<b>Total</b>	<b>75</b>	<b>33</b>	<b>107</b>	<b>35</b>	<b>50</b>	<b>65</b>	<b>4</b>	<b>23</b>	<b>126</b>	<b>518</b>

## 6) Fish market, Fishing Vessel and Fishery Product Section

There were 88 official controls on Fishery product establishments and fishing vessels. Samples of Aquaculture animals for residue testing were also taken.

## 7) Milk Hygiene and Cheeselets Section

### A. Traditional Dairy Sector

The Section has continued to carry out regular controls and follow-ups on farms producing Maltese traditional cheeselets (*gbejniet*) to verify the compliance with Council Regulation (EC) 852/2004 and Council Regulation (EC) 853/2004 of the Hygiene Package. The number of approved cheeselet producers has continued to increase.

National legislation to allow the continued use of traditional methods of production has been finalised.

### Activity 2019

Official controls are based on an updated list of registered holdings that according to the National Livestock Database have more than 10 sheep and/or goats.

All the holdings including those visited on the rapid survey inspection are inspected every 6 months with an assessment of different aspects of farm management and production, which incorporates:

1. **Animal Welfare:** compliance with relevant EU legislation and with the Farm Animals Protection Regulation (as per Animal Welfare Act, CAP. 439);
2. **Milking Hygiene:** animal disease signs and symptoms, milking procedures and milk storage; (as per CR 853 and Animal Welfare Act, CAP. 439).
3. **Dairy Production Hygiene assessment:** structure and equipment, HACCP plan, staff hygiene, plate count checks, microbiological checks, antimicrobial checks, transportation, wrapping and labelling of dairy products. (as per CR 853 and Animal Welfare Act, CAP. 439).
4. **Preliminary inspections/discussions** on holdings upon application for approval.
5. **Follow-up inspections:** for the issuing of conditional approvals and approvals.
6. **Yearly inspections** on approved establishments.

Table 1: Number of inspections from January to the end of December 2019

Inspection type	2019
-----------------	------

General inspection	394
Preliminary inspection	36
Inspection for approval	33
Audits	38
Total	514

Table 2: Number of newly approved ġbejna production rooms/establishments in 2019

<b>Traditional – cheeselets (Maltese Ġbejna )</b>	
Approvals Malta:	22
Approvals Gozo:	11
<b>Non-traditional- Establishment (Cheeselets are: Pasteurized/different-milk-species with flexibility as classified as small industry)</b>	
Approvals Malta:	1
Approvals Gozo:	0
Total end of 2019 new approvals	34
Total published by the end of 2019-including-previous-approved establishments:	81

TDU = Traditional Dairy Unit

Table 3: Number of preliminary/ Audit inspections in 2019

<b>Dairy –Milk Hygiene</b>	
Preliminary inspections Malta:	*
Early Audit farm inspections farm (Gozo)	29
Early Audit farm inspections (Malta)	5
Total farm insp.	34

<b>Dairy Establishments Inspections</b>	
<b>Malta</b>	10
<b>Gozo</b>	0
Total establishment insp./visited	10
* no new applicants in 2019	0
<b>Total</b>	44

Major emphasis is devoted to FBO premises hygiene & cleanliness, & the provision/use of medication under veterinary supervision.

A total of 300 milk samples for antibiotic testing (*sulphonamides, antibacterial substances, NSAIDs*, etc) were taken as part of the National Residue Plan (NRP) for 2019.

#### **RAW MILK DAIRY PRODUCERS**

The number of inspections at the Dairy establishment (collection and processing centre for Bovine milk) were 10. The number of inspections carried out on dairy farms were 34.

#### **FEED/ANIMAL NUTRITION**

##### **Feeding Stuffs and Animal Nutrition Section**

Feed Business Operators (FBOs) in Malta are registered according to article 9 of EU Regulation No 183/2005. Establishments carrying out certain activities, which can be considered ‘high risk’ such as the production and/or commercialisation of medicated feeds or feeds containing coccidiostats need approval under article 10 of the afore-mentioned Regulation.

During 2019, the Feeding Stuffs and Animal Nutrition Section registered a total of 7 feed businesses pursuant to article 9 to EU Regulation No 183/2005 as follows. These included: 3 feed distributors, 3 feed importers, 1 compound feed producer and 1 primary producer of feed.

Feed businesses in Malta can be grouped as follows:

<b>Type of Feed Business</b>	<b>Number</b>
Feed Mills	4 (1 includes medicated feed production/distribution)
other compound feed producers	4

Feed Stores	3
Feed Distributors	42
Feed Traders	1
Feed Importers	11
Feed Exporters	1
Feed Material Producer	7
On-Farm Feed Mixers	16
Feed Hauliers	12
Medicated Feed Distributors	3 (excluding feed mill above)
Primary Production of Feed	4

### **A. Inspections**

The following inspections of feed businesses were carried out: 1 compound feed producer, 7 on-farm feed mixers, 18 feed distributors, 7 feed material producers, 1 retailer, 1 feed store and 1 TMR mixers.

### **B. Registration of new Feed Businesses**

In the period of 1 January-31 December 2019, the Feeding stuffs and Animal Nutrition Section registered a total of 7 feed businesses pursuant to article 9 to EU Regulation No 183/2005 as follows. These included: 3 feed distributors, 3 feed importers, trader and 4 primary producers of feed.

This Section keeps a register of all feed businesses under its control. Registration is pursuant to article 9 of EU Regulation No 183/2005 and is online as per following link:

<https://agriculture.gov.mt/en/vrd/Documents/RegisterOfMalteseFeedBusinesses.pdf>

### **C. Residue Analysis**

This is applied on locally-produced compound feeds and on feed materials which enter Malta from the EU.

Based on the assessment of the results of the previous year, a sampling plan is generated for the year in question. The plan is forwarded to the Feeding Stuffs and Animal Nutrition Section so that sampling can be carried out. This section took a total of 47 feed samples under the survey scheme and 8 samples under the suspect scheme. Samples were of various types and from different types of feed businesses. Collected samples are forwarded to the National Veterinary Laboratory, which in turn subcontracts other laboratories to carry out the required testing, according to analyte or matrix.

In the case of non-compliances, the Section launches an investigation, in collaboration with other sections if necessary, in order to investigate the source/cause of such non-compliances.

#### **D. Sampling of feeds for GMOs**

Five samples of feed materials were taken from Kordin Grain Terminal, on behalf of importers to be analysed for the presence of any unauthorised GMOs. Only commodities coming directly from third countries were sampled, as those coming from EU were cleared/controlled by the respective Member States.

#### **E. Sampling of feeds for Processed Animal Proteins**

No samples were taken.

#### **F. Sampling of feeds for Salmonella**

No samples were taken.

#### **G. Investigations**

In 2019, this section performed a total of 6 investigations on one retailer, one feed distributor, two feed mills and 2 poultry layers farms. The investigations concerned the following issues:

- Detection of coccidiostats in broiler feed;
- Ionofores in eggs;
- Ionophores in compound feed;
- Report on a distributor selling mouldy and expired pet food with tampered BB dates;
- Report of expired dog treats retailed by a supermarket.

#### **H. Travel**

Officers from this Section were nominated as delegates to the Standing Committee meetings for Plants, Animal, Food and Feed (animal nutrition section) led by the Commission. These meetings regarded topics pertaining to feed additives, feed marketing issues, RASFF (Rapid Alert System Food and Feed) issues, contaminants in feed, not to mention draft Commission acts and annexes for vote by the Member State delegates as members of the Committee.

#### **I. Feed-related Investigations**

##### **1. Results 2019**

##### **A. Inspections/audits**

The following table provides a monthly breakdown of the inspections carried out in the course of 2019:

	<b>Month</b>
--	--------------

Type of Feed Business	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Commercial feed mill	3(A)	1(A)										
Commercial feed mill (medicated)												
Other compound feed producers					1							
Feed Distributors	1		2		5	1	3	3	2		1	
Feed hauliers												
Feed Retailer	1											
Medicated feed distributors			2(A)	1(A)								
Feed Material Producers		3(A)	1	2	1	1		1		1		
On-farm mixers	1					1	1		1	1		2
Feed Store		1										
TMRs						2		2				
Feed Importers	1				1	1	1					
<b>Totals</b>	<b>Inspections: 43</b>					<b>Audits: 10</b>						

A=audit

### B. Registration of New Feed Businesses

Type of Feed Business	Number of new registrations
Feed Distributors	
Medicated feed distributors	3
Feed Material Producers	
Feed Importers	3
Feed traders	

Other compound feed producers	
Feed Transporters	
Primary producers of feed	1
<b>Total</b>	<b>7</b>

### C. Residues Analysis

The following tables list, respectively the sampling carried out in the commercial feed sector (by analyte and feed type) and the on-farm feed compounding activity according to analyte and feed type.

*Table 1: Samples collected from commercial feed operators (commercial feed mills) according to feed type and analyte*

	Feed material (multispecies feed)	Layers feed	Poultry feed	Swine feed	Bovine feed	Rabbit feed
<b>organochlorine compounds</b>	1					
<b>Nicarbazin</b>						
<b>Fluorine</b>					1	
<b>Vomitoxins</b>						
<b>Fumonisin</b>	1					
<b>tetracyclines/macrolides/sulphonamides</b>						
<b>Antibacterial substances</b>		1	1	1	2	1
<b>Pyrethroids</b>	1					
<b>Heavy metals</b>			1	1	1	
<b>Dioxins/dioxin-like PCBs</b>	1					
<b>Ionophores</b>		1	1			
<b>Benzimidazoles</b>				1		
<b>Trenbolone</b>						
<b>Zearalenol/zearalenone</b>					1	
<b>Stilbenes</b>						
<b>Aflatoxins</b>	2			2		
<b>Copper</b>					1	



<b>Nitroimidazoles</b>				1		
<b>Ochratoxin A</b>						
<b>Avermectins</b>				1		
<b>Zeranol</b>						
<b>Anti Coccidials</b>						2

*Table 2: Samples collected from on-farm feed compounders according to feed type and analyte; total number of samples taken: 4*

	<b>Feed Materials</b>	<b>Layers feed</b>	<b>Swine feed</b>	<b>Poultry feed</b>
<b>nicarbazin</b>	-	-	1	-
<b>antibacterial substances</b>	-	1	-	-
<b>chloramphenicol</b>	-	-	2	-
<b>aflatoxins</b>	-	-	1	-

#### **D. Sampling for GMOs**

Pursuant to Commission Regulation 619/2011, no samples for GMOs were taken in 2019.

#### **E. Sampling for Salmonella (survey)**

No samples were taken for Salmonella.

#### **F. Feed-Related Investigations**

<b>Feed Establishment</b>	<b>Samples taken</b>	<b>Intended Analysis</b>
Feed mill	2 x pig feed	Ionophores
	6 x poultry feed	Ionophores
On Farm Mixer	3 x poultry	Ionophores

## TRADE UNIT

The unit is made of BIP and Intra-trade sections and monitors controls intra community trade and import and export of animal and goods<sup>1</sup>.

The Border Inspection Post (BIP) section includes the following BIPs: Marsaxlokk (MTMAR1), Luqa (MTLUQ4), Valletta (MTMLA1), all of them approved under Annex 1 of Commission Decision 821 /2009.

The main task of the BIPs is to ensure that products of animal origin (POAO) and live animals entering to the EU are safe and meet the specific conditions laid down in the Community and Maltese legislation. The imported live animals and products of animal origin present the highest level of risks as they can transmit serious human and animal diseases. Therefore, it is necessary to subject them to specific controls at their point of entry. A consignment of live animals or a product of animal origin can only enter into the EU, if it has satisfactorily undergone the specific checks and a Common Veterinary Entry Document (CVED) is issued.

Three Veterinary Officers – One Senior Veterinary Officer and two Veterinary Officers - are in charge of the all activities carried out in the three BIPs. They are assisted by a total of ten other officers, as follows:

- 04 (Four) SVSO's
- 03 (Three) VSO's/AVSO's
- 03 (Three) Senior Operatives

In the year 2019, all consignments originated in third countries either POAO or live animals, which have entered the EU through one of the three BIPs, were checked in accordance with to the Community and Maltese legislations.

### ACTIVITY 2019

#### 1. IMPORT

- POAO<sup>2</sup> MTMAR1 (See table 1,2,3)

A total of 1799 consignments of POAO were checked at the BIPs. Of those, 585 were inspected at MTMAR1 for internal market, 29 were inspected at MTMAR1 in transshipment to EU, and 1185 consignments in transshipment to third countries.

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<sup>1</sup> LEGEND:

ABBREVIATION	MEANING
HC	Human Consumption
NHC	Non-Human Consumption
POAO	Products of Animal Origin

For all imported consignments a documental, identity and physical check was carried out in accordance to the requirements sets in the Council Directive 97/78.

- POAO MTLUQ 4 (See table 4)

122 consignments POAO were imported and checked at the BIP MTLQ4. 121 out of 122 were consignments destined for human consumption. Fresh fish and lobsters were the products imported. 1 consignment, non-human consumption, was received (bird skins).

Of all human consumption products received at MTLQ4, Senegal and Morocco were the countries of origin which exported most consignments, with a total number of 69 from Senegal, and 47 from Morocco, out of 115. All of them were fresh fish, which were checked in line with community legislation

- LIVE ANIMALS MIA (See table 5)

With regards of live animals, a total of 146,880 were inspected by the BIP section.

228 were dogs and cats arriving from third countries as non-commercial movement, and inspected at the Malta International Airport. Last year, Russia was the country from which most of pets originated, followed by Switzerland and USA.

25 pets were imported as commercial movement, mainly imported from Russia.

A total of 146,627 were live fish imported during the year 2019. All live animals and the documentation which accompanied them, were examined by the Official Veterinarians to ensure that they were in line with the EU requirements for animal health and welfare.

- REJECTED CONSIGNMENTS

With regards to consignments presented for inspection at BIP MTMAR1, during the year 2019, 72 consignments were rejected, mainly transshipments.

No consignment of fresh fish was rejected at BIP MTLUQ4 during the inspections carried out in the year 2019.

- DOG & CAT FUR/ SEAL PRODUCTS

In line with the requirements set by Regulation EC1523/2007 on banning the placing on the market and the import to, or export from, the Community, of cat and dog fur, and products containing such fur, and in line also with Regulation EC 1007/2009 on trade of seal products, this Section performed different levels of checks on all leather consignments imported from third countries.

## **2. EXPORT**

With regards to export, this section had carried out several inspections of consignments prior to their export. As result of these inspections, export health certificates were issued by the Official Veterinarians.

A total of 5 consignments of pet food were exported to Lebanon, Kuwait, Saudi Arabia, Israel and Malaysia.

A total of 3 consignments of cheese were exported to Libya.

1 consignment of Tuna was exported to Seychelles.

A total of 20,755 live animals were exported during 2019 from Malta to non-EU countries. Of these, 20,731 were birds mainly exported to Jordan, Kuwait, Lebanon, Libya and Viet-Nam.

On those occasions, prior the departure, Official Veterinarians examined the animals and then issued the certificates required by the different authorities.

### **3. FMD LIBYA and POAO seized from passengers or found in parcels.**

Since January 2012, after the outbreaks of Foot and Mouth Disease (FMD) in Libya, the BIP section was involved in the supervision of the collection of the waste and the disinfection of the trailers/containers unloaded from vessels arriving for Libya. The section was also involved in the collection and destruction of all undeclared POAO and food confiscated at the airport, by Custom personnel, from passengers arriving from Libya.

During 2019, 113 vessels have received clearance to berth by the BIP section.

A total 2,072.35 kg of products were seized, including both POAO brought in by passengers at the airport and POAO found in parcels. Personal imports through MIA were 2,031.75 kg, while those through parcel post were 40.60 kg. All POAO seized were disposed by incineration.

## **4. LABORATORY**

- RE-ENFORCED CHECKS

In response to RASFF notifications triggered by different EU Member States, and within the Re-enforced checks program launched by the Commission at the beginning of the year, this section, on several occasions, was asked to collect samples of particular type of products. The samples were then sent to the laboratory to undergo specific tests.

- RESIDUES PLAN (see table 6)

Following the annual sampling plan provided, a residues sampling was carried out, through the all year, on goods arriving from third countries and presented to the BIP for inspection.

## **5. OTHER**

- INTERTRACE TRANSHIPMENTS CONSIGNMENTS:

The Section is now adopting the System Intertrace for consignments in transshipments. A total of 1,251 consignments for total of 2,220 containers were in transshipments and were checked by the Section.

- MOU

A Memorandum of Understanding between Veterinary Regulation Directorate and the following authorities was signed during the year 2015: Plant Health and Agriculture Dep.

A Memorandum of Understanding on how to manage the shared use of the BIPs facilities has been signed between Veterinary Regulation Directorate, Plant Health, Customs and Port Health, after several meetings held with the different authorities involved.

## 6. INTRA-COMMUNITY TRADE

The section is responsible for the controls on live animals, food of animal origin, and feed, subjected to trade within the European Union.

One Veterinary Officer is in charge of the all activities carried out by the Section.

The checks are normally carried out at the following Entry Points:

1. Valletta Grand Harbour (Valletta)
2. Marinas (Sliema)
3. Domestic EU Flights (Airport, Luqa)
4. Staging Post (Marsa)

The intra trade section is responsible for all the products of animal origin and live animals that are moved from EU Member States to Malta. In year 2019, the section performed several inspections throughout the year. These are the amounts of animals that have been controlled :

*Table 1: Animals moved to Malta in 2019*

<b>Animal species</b>	<b>Total</b>
Fish	1,899
Horses	410
Bovines	38
Swines	1,810
Reptiles	1,150
Dogs	17
Turkey	800
Birds of prey	2
Poultry	554,237
Bees	12,487
<b>Total</b>	<b>682,225</b>

*Table 2: Animals moved outside Malta to EU in 2019*

<b>Animal species</b>	<b>Total</b>
Bear	1
Horses	88
Bees	8,482
Swines	100
Dogs	96
Pigeons	109,375
Parrots	2
<b>Total</b>	<b>118,144</b>

## 6. TABLES

*Table 1. POAO MTMARI (Internal Market)*

<b>Country of Origin</b>	<b>Country of Destination</b>	<b>Number of Consignments</b>
Argentina	Malta	19
Australia	Malta	11
Botswana	Malta	8
Brazil	Malta	19
Canada	Malta	7
China	Malta	37
Ecuador	Malta	19
Ghana	Malta	2
India	Malta	1
Indonesia	Malta	14
Kenya	Malta	2
Korea Republic of	Malta	16
Mauritius	Malta	17
Morocco	Malta	159
Namibia	Malta	1
New Zealand	Malta	19
Papua New Guinea	Malta	2
Peru	Malta	6
Philippines	Malta	28
Russian Federation	Malta	1
Senegal	Italy	80
Senegal	Malta	25
Seychelles	Malta	1
South Africa	Malta	1
Taiwan	Malta	1
Tanzania	Malta	3

Thailand	Malta	53
Turkey	Malta	10
Uganda	Malta	1
United States	Malta	1
Viet Nam	Malta	20
<b>Total</b>		<b>585</b>

Table 2. POAO MTMARI (Transshipment to EU)

Country of Origin	Country of Destination	Number of Consignments
China	Italy	3
India	Spain	1
Thailand	Italy	20
Viet Nam	Italy	4
Viet Nam	Monaco	1
<b>Total</b>		<b>29</b>

Table 3. POAO MTMARI (Transshipment to Third Country)

Country of Origin	Country of Destination	Number of Consignments
Algeria	Viet Nam	24
Algeria	China	2
Argentina	Tunisia	1
Argentina	Algeria	5
Argentina	China	3
Argentina	Jordan	2
Argentina	Saudi Arabia	30
Argentina	Taiwan	2
Argentina	Yemen	1
Australia	Tunisia	1
Australia	Morocco	1
Brazil	Albania	10
Brazil	Algeria	1
Brazil	China	8
Brazil	Egypt	82
Brazil	North Macedonia	6
Brazil	Iraq	1
Brazil	Jordan	20
Brazil	Kosovo	21
Brazil	Kuwait	9
Brazil	Lebanon	63
Brazil	Libya	141
Brazil	Macedonia	1
Brazil	Malaysia	13
Brazil	Mauritania	1
Brazil	Myanmar	1

Brazil	North Macedonia	1
Brazil	Oman	13
Brazil	Qatar	5
Brazil	Saudi Arabia	177
Brazil	Serbia	1
Brazil	Singapore	2
Brazil	Tunisia	16
Brazil	Turkey	9
Brazil	United Arab Emirates	127
Brazil	Viet Nam	6
Brazil	Yemen	5
Canada	Kosovo	1
Chile	Ukraine	1
China	Albania	1
China	Libya	3
China	Tunisia	2
Ecuador	Albania	2
Ecuador	Tunisia	1
Egypt	Algeria	1
Egypt	Haiti	5
Egypt	Libya	2
Egypt	Senegal	1
North Macedonia	Tunisia	1
Hong Kong	Algeria	1
Hong Kong	Tunisia	1
India	Algeria	7
India	Dominican Republic	1
India	Ecuador	1
India	Lebanon	6
India	Libya	1
India	Mexico	1
India	Tunisia	80
India	United States	1
Indonesia	Turkey	2
Japan	Libya	3
Jordan	Libya	3
Korea	Algeria	1
Lebanon	Congo	1
Lebanon	Liberia	4
Malaysia	Tunisia	1
Mauritania	China	1
Mauritania	Tunisia	1
Mauritius	Tunisia	2
Montenegro	Hong Kong	1
Morocco	Tunisia	2
Morocco	Turkey	1
Namibia	Libya	1
New Zealand	Algeria	1
New Zealand	Libya	1
New Zealand	Tunisia	1
Oman	Libya	6
Oman	Tunisia	1



Paraguay	Lebanon	2
Peru	Algeria	5
Peru	Bahrain	1
Peru	Libya	1
Serbia	China	1
Serbia	Russia	6
Serbia	Viet Nam	3
Seychelles	Tunisia	3
Seychelles	Turkey	1
Thailand	Egypt	2
Thailand	Libya	33
Thailand	North Macedonia	1
Thailand	United Arab Emirates	1
Tunisia	Congo	1
Tunisia	Egypt	2
Tunisia	Gambia	1
Tunisia	Guinea	1
Tunisia	Indonesia	3
Tunisia	Japan	1
Tunisia	Korea Republic of	20
Tunisia	Lebanon	1
Tunisia	Liberia	4
Tunisia	Libya	1
Tunisia	Madagascar	1
Tunisia	Qatar	1
Tunisia	South Korea	5
Tunisia	Sudan	1
Tunisia	Myanmar	1
Tunisia	Taiwan	1
Tunisia	Thailand	9
Tunisia	Turkey	1
Tunisia	Viet Nam	7
Turkey	Congo	2
Turkey	Jordan	1
Turkey	Libya	3
Turkey	Maldives	1
Turkey	Serbia	1
Turkey	Somalia	1
Turkey	Venezuela	2
Ukraine	Congo	3
Ukraine	Cote D'Ivoire	1
Ukraine	Gabon	1
Ukraine	Gambia	6
Ukraine	Guinea	5
Ukraine	Haiti	1
Ukraine	Lebanon	1
Ukraine	Liberia	2
Ukraine	Libya	11
Ukraine	Mauritania	17
Ukraine	Saudi Arabia	2
Ukraine	Sierra Leone	2
Ukraine	Somalia	5

Ukraine	Tunisia	2
Ukraine	Zambia	1
United Arab Emirates	Mauritania	1
United Arab Emirates	Tunisia	2
United States	Gambia	2
United States	Serbia	2
Viet Nam	Albania	1
Viet Nam	Algeria	2
Viet Nam	Kosovo	2
Viet Nam	Libya	2
Viet Nam	Tunisia	3
<b>Total</b>		<b>1185</b>

Table 4. POAO MTLUQ 4

Country of Origin	Country of Destination	Number of Consignments
Canada	Malta	2
Greenland	Malta	1
Morocco	Malta	47
Senegal	Malta	69
United States	Malta	3
<b>Total</b>		<b>122</b>

Table 5. Live Animals MIA

Country of Origin	No. of Consignments	Commodity
Indonesia	28	Live fish
Israel	11	Live fish
Kenia	2	Live fish
Malaysia	13	Live fish
Philippines	4	Live fish
Singapore	9	Live fish
Sri Lanka	19	Live fish
Thailand	27	Live fish
United States	1	Live fish
Viet Nam	9	Live fish
Belarus	4	Dog
Russian Federation	16	Cats/Dogs
<b>Total</b>		<b>143</b>

Table 6. Laboratory

Commodity	Country Of Origin	Motivation	Laboratory Tests	Number Of Samples
1604	China	Re-enforce check	Albumin	1

1604	Ecuador	Re-enforce check	Histamine	1
0304	Viet Nam	Random	PCB's	1
1604	Mauritius	Random	Histamine	1
0304	Viet Nam	Random	PCB's	1
0304	Viet Nam	Random	PCB's	1
1604	Philippines	Random	Histamine	1
1602	Brazil	Random	Chloramphenicol	1
1604	Philippines	Random	Histamine	1

# **NATIONAL VETERINARY LABORATORY**

## **Introduction**

The National Veterinary Laboratory (NVL) falls under the operational control of the Animal Health and Welfare Department (AHWD) and reports directly to the Director General AHWD and the Minister. The laboratory is established by Part III of CAP 437 of the Veterinary Services Act. The laboratory is a primary production testing laboratory. Activities covered include: (i) surveillance programmes through national plans and surveys (ii) investigation of suspects (iii) border inspection residues controls (iv) national reference services.

The NVL fulfils various roles including:

- Animal Disease Surveillance such as Enzootic Bovine Leucosis, Foot and Mouth, Bluetongue and Classical Swine Fever;
- Food Health Surveillance such as Trichinella and Transmissible Spongiform Encephalopathy;
- Zoonotic Disease Surveillance such as Avian influenza, Brucella and Salmonella;
- Veterinary Drug Residue Surveillance such as antimicrobials, medicinal products and contaminants in foods of animal origin;
- Antimicrobial Resistance Monitoring Programme.

The laboratory is responsible for microbiological and chemical analysis of samples collected by the Veterinary Regulation Directorate (VRD) Units and also provides technical and scientific support for such. In line with CAP 437, the NVL is also responsible for Veterinary Medicines thereby implementing official controls in conjunction with the VRD.

The NVL employs a quality management system and is accredited by the National Accreditation Bureau (NAB-Malta) for six test parameters according to ISO/IEC 17025:2017 standard.

The NVL is the National Reference Laboratory (NRL) for all animal diseases under EU legislation and for residues of veterinary medicines and certain contaminants in food of animal origin. As an NRL, the NVL must fully comply with Regulation No.652/2017, concerning official controls. Presently, the NVL does not have the necessary expertise to fulfil all the NRL obligations and thus the laboratory liaises with laboratories from other Member States to assist it in this role.

## **1.0 Chemical Analysis Section**

The NVL is responsible for analysis or subcontracting of the Malta National Residue Plan (MNRP) in accordance with Council Directive 96/23. Just over 1,900 samples are collected from different sample collection points including slaughterhouses, farms etc. Samples arise from different species-matrix combinations. This ensures that residues of veterinary drugs and environmental contaminants are not present in animal products intended for human consumption. The chemistry section is also responsible for two other plans, one covers products imported from third countries and the other includes surveys conducted by different units

within the VRD. Suspect samples are also taken care of by the Chemical Analysis Section. Samples which are not analysed at the laboratory are subcontracted to ISO 17025 accredited European laboratories which are also validated for the intended test method.

The NVL carries out in-house screening for some antibacterial substances in muscle and eggs using a plate diffusion method, quinolones in poultry muscle using ELISA kits and sulphonamide residues on muscle samples excluding equine and fish, eggs and milk. Both test methods are validated and included in the accreditation scope. The laboratory is has also validated tetracyclines, macrolides and erythromycin analysis on poultry muscle using ELISA and is also working to include the analysis of other classes of antibacterial substances in other matrices using commercial ELISA kits within its accreditation scope.

### 1.1 Screening for Sulphonamides using TLC at the NVL

Sulphonamide testing is done by a qualitative screening method using thin layer chromatography. When screening results show presence of sulphonamides, the sample in question is subcontracted to an accredited foreign laboratory for quantitative analysis. Table 1 hereunder shows the number of samples analysed for sulphonamides during the year 2019. All samples analysed did not show any presence of sulphonamides except for 1 milk sample which was then subcontracted for confirmatory analysis. The latter analysis showed that the sulphonamide content was below the maximum residue level stipulated by Commission Regulation 37/2010.

*Table 1: Sulphonamides analysis performed at the NVL during the year 2019*

Matrix	Number of Samples Analysed
Milk	211
Eggs	75
Muscle	5

### 1.2 Screening for Antibacterial Substances using the Plate Diffusion Method at the NVL

This test is accredited for muscle tissue of different species and egg samples. Samples which show presence of antibacterial substances are subcontracted to foreign laboratories for confirmatory analysis. The type and number of analysis carried out using the plate diffusion method for antibacterial substances during the year 2019 is summarised in the table below.

*Table 2: Analysis for Antibacterial Substances performed at the NVL during the year 2019*

Scheme	Matrix	Number of Samples Analysed
National Plan	Muscle	40
National Plan	Eggs	74
Suspects	Muscle	66
Salmonella Control Programme	Poultry Muscle	415

Positive screened samples resulting from the analysis carried out at the NVL were sent to a foreign laboratory accredited for the specific confirmatory analysis. One swine muscle sample submitted to the lab as a suspect sample was confirmed non-compliant for Gentamycin under

Regulation 37/2010. Two poultry muscle samples collected under the SNCP scheme were confirmed non-compliant under Regulation 1177/2006 due to presence of quinolones.

### 1.3 Analysis of veterinary drug residues and contaminants carried out by foreign laboratories

Due to lack of equipment and expertise, the vast majority of veterinary drug residue analysis is subcontracted to foreign laboratories with accredited and validated methods. The tables in Appendix I list all the residue analysis that was performed by foreign laboratories during the year 2019.

## 2.0 Serology

### 2.1 Brucellosis Surveillance Programme

The Rose Bengal Test (RBT) is routinely performed on blood samples collected on-farm and during slaughter. Samples which give result positive during screening are sent abroad to an accredited MS NRL for further analysis by the Complement Fixation Test. All samples tested were negative.

Bulk milk is tested every three months on dairy-producing farms. The samples are screened for brucellosis with the Milk Ring Test (MRT).

*Table 3: Brucellosis Testing during the Year 2019*

Test Type	No. of Tested Samples
Rose Bengal Test	38,889
Milk Ring Test	332

### 2.2 ELISA testing on Animal Diseases

The NVL carries out a number of ELISA screening tests for animal diseases in line with Commission Directives and Regulations.

*Table 4: ELISA Testing during the Year 2019*

Test Type	No. of Tested Samples
Enzootic Bovine Leukosis - Serum	8,999
Enzootic Bovine Leucosis - Milk	332
Avian Influenza Virus	208
Bluetongue Virus	480
Classical Swine Fever Virus	1,059

Any samples screened positive with ELISA are sent to MS NRLs for confirmatory analysis.

### 2.3 Transmissible Spongiform encephalopathies (TSE)

TSE testing is done in accordance with Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. All samples tested in 2019, resulted negative. The number of analysis performed according to the different categories are listed in the table 5 below.

Table 5: TSE Analysis conducted during the Year 2019

Category	No. of Tests
Fallen Bovine	253
Emergency Bovine	61
Healthy Slaughter Ovine	131
Fallen Ovine	339
Healthy Slaughter Caprine	129
Fallen Caprine	160
Others	5
<b>Total</b>	<b>1,078</b>

### 3.0 NVL - Parasitology

#### 3.1 Surveillance of *Trichinella spiralis*

*Trichinella* testing is carried out on all fattening pigs, sows and boars and all equines slaughtered for human consumption. The method is based on Commission Implementing Decision (EU) No 1375/2015 laying down specific rules on official controls for *Trichinella* in meat. *Trichinella* testing is done on batches of generally 100 samples each. All samples tested in 2019 resulted negative.

Table 6: *Trichinella* Samples Tested during the Year 2019

Matrix/Species	No. of Tests
Swine	52,147
Equine	1
<b>Total</b>	<b>52,148</b>

### 4.0 Microbiology section

#### 4.1 Salmonella in Poultry

The aim of the Salmonella National Control Programme - SNCP is to monitor and control zoonotic Salmonella infection in *Gallus Gallus* flocks (broilers and laying hens) according to provisions laid out in Commission Directive 2160/2003. Over 540 samples were tested at the NVL for Salmonella isolation.

##### 4.1.1 Broiler Flocks

According to the Animal Welfare Act. 439 LN 119 of 2005, persons or establishments rearing or keeping more than 20 broilers, should be licensed by the CA. All registered broiler flocks in Malta and Gozo are covered by the SNCP.

The criteria established by Council Regulation (EC) 2160/2003 and Commission Regulation (EC) no 200/2012, aim to reduce the prevalence of Salmonella by achieving a reduction of the maximum annual percentage of flocks of broilers remaining positive for Salmonella enteritidis

and *Salmonella typhimurium* including Monophasic *Salmonella typhimurium* serotypes with the antigenic formula 1,4, [5],12:i equal to 1 % or less.

During the year 2019, 238 flocks of broiler were tested at the NVL. Flocks are screened for antimicrobial substances by the NVL even those that are non-official samples.

Table 7: Serovars Isolated in Broiler Flocks–Year 2019

Sample Type	Type of Serovar	Amount
Broilers	Monophasic <i>Salmonella Typhimurium</i>	2
	S. Type V	1
	<i>S.Livingstone</i>	1
	<i>S.Give</i>	5
	<i>S.Haifa</i>	22
	<i>S.Infantis</i>	9
	<i>S.Kentucky</i>	22
	<i>S. Panama</i>	1
	<i>S.Menden</i>	1
	<i>S. Gallinarium</i>	1
	<i>S. Virchow</i>	1
	<i>S. Tomegbe</i>	2
	<i>S. Mbandaka</i>	1

### Positive broiler flocks for targeted serovars during the year 2019

**No. of Flocks:** 2

**Serovar isolated:** All flocks having one of the targeted serovars were infected with Monophasic *Salmonella Typhimurium*

#### 4.1.2 Laying Hen flocks

Laying hen flocks covered by the SNCP include commercial flocks in layer farms registered in terms of the Egg Marketing Standard Regulations LN 345 of 2003 under Chapter 427 - The Product Safety Act. In accordance with this law each individual egg-laying farm is given a unique identity number that has to be printed on all the eggs produced intended for commercial purpose. The SNCP also covers rearing flocks of future laying hens.

The SNCP does not apply to flocks for private domestic use or leading to the direct supply, by the producer of small quantities of table eggs to the final consumer or to local retail establishments.

The criteria established for laying hens by Council Regulation 2160/2003 and Commission Regulation (EU) 517/2011, aim to reduce the prevalence of *Salmonella* by achieving a reduction of the maximum annual percentage of flocks of broilers remaining positive for *Salmonella enteritidis* and *Salmonella typhimurium* including Monophasic *Salmonella typhimurium* serotypes with the antigenic formula 1,4, [5],12:i equal to 2 % or less of positive flocks of adult laying hens. The Union target shall be achieved every year based on the monitoring of the previous year.

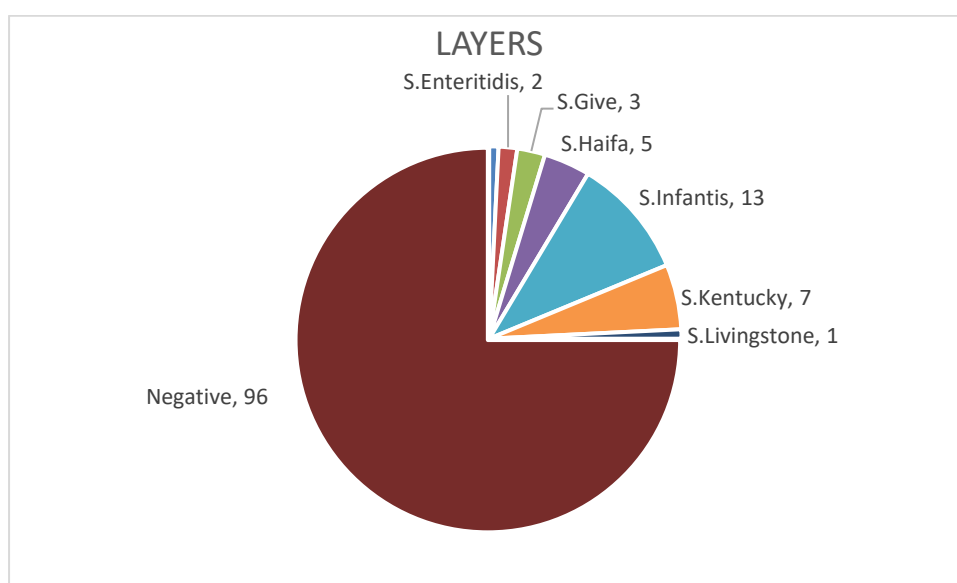


Table 8: Number of Analysis Performed in Layer Flocks –Year 2019

Sample Type	Salmonella Positive	Salmonella Negative	Total
Layers	32	96	128
Layers Retest	0	4	4
Layers Day Olds	0	5	5
Layers Cleaning	0	8	8
<b>Total</b>	<b>32</b>	<b>113</b>	<b>145</b>

NB. The results are not reported in relation to the flock as defined in EU legislation but as individual tests.

Figure 1: Distribution of Salmonella Serovars in Layers–Year 2019



The data above does not take account of repeats or flocks but as total numbers of isolates

#### 4.1.4 Breeding Flocks / Turkey Flocks

At present, there are no local breeding flocks of broilers or layers in Malta. There are also no commercial registered turkey farms.

#### 4.2 Salmonella Analysis in Swine Carcasses

The National Veterinary Laboratory on behalf of the Competent Authority carries out Salmonella Analysis on official swine carcass swabs in accordance to Commission Regulation (EC) 882/2004. This analysis is performed following ISO 6579 and accredited under ISO 17025. The swine slaughterhouse is obliged to have less than 3 carcasses with the presence of Salmonella in 50 samples which are taken in 10 consecutive sampling sessions.

Table 9: Analysis performed for Salmonella isolation on Swine Carcasses – Year 2019

Sample Type	Salmonella Positive	Salmonella Negative	Total
Swine carcass	5	55	60

Table 10: Serovars Isolated in Swine Carcasses– Year 2019

Sample Type	Type of Serovar	Amount
Swine carcass	<i>S. Enteritidis</i>	1
	<i>S. Kentucky</i>	1
	<i>S. Croft</i>	2
	<i>S. Give</i>	1
	<i>S. Infantis</i>	1

#### 4.3 Antimicrobial Resistance Monitoring Programme in accordance to Commission Implementing Decision 652/2013

According to Directive 2003/99/EC Member States shall monitor the occurrence of antimicrobial resistance in zoonotic agents. The NVL carries out monitoring for Antimicrobial Resistance on different animal species on alternate years. During the year 2019, the monitoring was carried out on swine samples.

Decision 2013/652/EU on the monitoring and reporting of AMR in zoonotic and commensal bacteria, lays down detailed rules for the harmonised monitoring and reporting of antimicrobial resistance (AMR) to be undertaken by the Member States in line with Article 7(3) and 9(1) of Directive 2003/99/EC and Annex II (B) and Annex IV.

The monitoring and reporting covers *Salmonella spp.*, Indicator commensal *Escherichia Coli* and ESBL/AmpC/Carbapenemases in *Salmonella* and *E. Coli*.

#### 4.4 Antimicrobials (AMR) Monitoring

Each of the isolates was tested using microbroth dilution method with ‘Thermoscientific EUVSEC Sensititre Plates’ where the ranges of these plates were as stipulated in the Annex, of Commission Implementing Decision of 12 November 2013.

The results were then interpreted using the ‘epidemiological cut off values’ as described in the Annex, of Commission Implementing Decision of 12 November 2013 and updated with the latest updates from World Health Organisation. The serovars were considered as being positive when the epidemiological cut-off value stipulated was exceeded.

Isolates which were tested on the first panel of antimicrobials in accordance to Table 1 of the commission implementing decision and which were found resistant to Cefotaxime, Ceftazidime or Meropenem when compared to the ‘epidemiological cut-off values’ of Table 1 of the Commission Implementing Decision, as well as, all E-coli isolates which showed presumptive ESBL-, AmpC- or Carbapenemase –producing traits on the Cefotaxime plates, were further analysed for extended susceptibility testing.

Testing for extended susceptibility was performed using ‘Thermoscientific EUVSEC2 Sensititre Plates’ which were in-line with the ranges as stipulated in Table 4 of Commission Implementing Decision of 12 November 2013.

The results which were obtained from these analyses were then re-evaluated and re-interpreted to the 'Epidemiological Cut-Off values' as specified in Table 4 of Commission Implementing Decision of 12 November 2013.

The details of the AMR analysis for 2019 are to be found in Appendix 2.

Appendix I – All samples received within the Chemical Analysis Section

Table 13 – Samples analysed for Group A Substances during the Year 2019

C- Compliant, NC- Non-Compliant

Group		Jan		Feb		March		April		May		June		July		Aug		Sept		Oct		Nov		Dec		TOTAL	
		C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC
Stilbenes	A1 - National Plan	0	0	0	0	1	0	4	2	1	0	1	0	2	0	0	0	3	0	3	0	1	0	1	0	17	2
	A1 - Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	A1 -Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	A1 - Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>A1 - Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>4</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>17</b>	<b>2</b>
Antithyroid Agents	A2 - National Plan	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	5	0
	A2 - Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	A2 -Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	A2 - Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>A2 - Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>0</b>
Steroids	A3 - National Plan	0	0	0	0	0	0	3	0	2	1	4	1	0	0	2	0	2	1	5	2	2	0	1	0	21	5
	A3 - Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	A3 -Survey	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	A3 - Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>A3 - Total</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>4</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>5</b>	<b>2</b>	<b>2</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>21</b>	<b>6</b>
Resorcyclic Acid Lactones	A4 - National Plan	0	0	0	0	0	0	1	1	1	0	3	0	4	0	1	1	2	0	2	0	0	0	1	0	15	2
	A4 - Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	A4 -Survey	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	A4 -Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>A4 - Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>16</b>	<b>2</b>

Group		Jan		Feb		March		April		May		June		July		Aug		Sept		Oct		Nov		Dec		TOTAL	
		C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC
Beta Agonists	A5 - National Plan	0	0	0	0	0	0	5	0	1	0	2	0	2	0	4	0	0	0	3	0	0	0	4	0	21	0
	A5 – Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	A5 -Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	A5 -Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>A5 – Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>21</b>	<b>0</b>
Nitrofurans and Metabolites, Nitroimidazoles, Chloramphenicol, Dapsone	A6 - National Plan	1	0	30	0	25	0	53	0	20	0	17	0	84	1	74	0	25	0	40	0	21	0	29	0	419	1
	A6 – Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
	A6 -Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	2	0
	A6 -Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
	<b>A6 – Total</b>	<b>1</b>	<b>0</b>	<b>30</b>	<b>0</b>	<b>25</b>	<b>0</b>	<b>53</b>	<b>0</b>	<b>20</b>	<b>0</b>	<b>17</b>	<b>0</b>	<b>84</b>	<b>1</b>	<b>76</b>	<b>0</b>	<b>25</b>	<b>0</b>	<b>41</b>	<b>0</b>	<b>22</b>	<b>0</b>	<b>29</b>	<b>0</b>	<b>423</b>	<b>1</b>

Table 14 – Samples analysed for Group B Substances during the Year 2019

C- Compliant, NC- Non-Compliant

Group		Jan		Feb		March		April		May		June		July		Aug		Sept		Oct		Nov		Dec		TOTAL	
		C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC
Antibacterial Substances	B1-National Plan	0	0	41	0	36	0	82	0	28	0	19	0	152	0	136	0	40	0	44	0	28	0	72	0	678	0
	B1- Suspect	9	0	11	0	5	0	11	0	9	0	2	0	8	0	6	0	3	2	8	0	2	0	2	0	76	2
	B1 - Survey	0	0	0	0	2	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	1	0	8	0
	B1- Confirmatory	0	0	0	0	0	0	0	1	1	0	3	0	3	1	2	0	0	0	5	0	1	0	0	0	15	2
	B1- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>B1- Total</b>	<b>9</b>	<b>0</b>	<b>52</b>	<b>0</b>	<b>43</b>	<b>0</b>	<b>93</b>	<b>1</b>	<b>38</b>	<b>0</b>	<b>24</b>	<b>0</b>	<b>163</b>	<b>1</b>	<b>149</b>	<b>0</b>	<b>43</b>	<b>2</b>	<b>57</b>	<b>0</b>	<b>31</b>	<b>0</b>	<b>75</b>	<b>0</b>	<b>777</b>	<b>4</b>

Anthelmintics	B2a-National Plan	0	0	0	0	0	0	1	0	4	0	5	0	10	0	9	0	3	0	4	0	8	0	15	0	59	0	
	B2a- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B2a - Survey	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	3	0
	B2a- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B2a- Imports	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	<b>B2a- Total</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>10</b>	<b>0</b>	<b>11</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>8</b>	<b>0</b>	<b>15</b>	<b>0</b>	<b>63</b>	<b>0</b>	
Anticoccidials	B2b-National Plan	0	0	19	0	14	0	19	0	15	0	14	0	24	0	19	0	26	2	16	0	14	0	19	0	199	2	
	B2b- Suspect	0	1	5	0	2	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13	1	
	B2b - Survey	1	0	0	0	0	0	5	0	3	0	0	0	0	0	3	0	1	0	0	0	0	0	1	0	14	0	
	B2b- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	B2b- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	<b>B2b- Total</b>	<b>1</b>	<b>1</b>	<b>24</b>	<b>0</b>	<b>16</b>	<b>0</b>	<b>30</b>	<b>0</b>	<b>18</b>	<b>0</b>	<b>14</b>	<b>0</b>	<b>24</b>	<b>0</b>	<b>22</b>	<b>0</b>	<b>27</b>	<b>2</b>	<b>16</b>	<b>0</b>	<b>14</b>	<b>0</b>	<b>20</b>	<b>0</b>	<b>226</b>	<b>3</b>	
Carbamates and Pyrethroids	B2c-National Plan	0	0	0	0	0	0	0	0	1	0	0	0	2	0	3	0	2	0	2	0	0	0	0	0	10	0	
	B2c- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	B2c - Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	
	B2c- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	B2c- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	<b>B2c- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>11</b>	<b>0</b>	
Sedatives	B2d-National Plan	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	0	0	3	0	
	B2d- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	B2d - Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	B2d- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	B2d- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	<b>B2d- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>0</b>	

NSAIDs	B2e-National Plan	0	0	11	0	10	0	27	0	1	0	1	0	61	0	60	0	5	0	11	0	8	0	24	0	219	0
	B2e- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
	B2e - Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B2e- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B2e- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>B2e- Total</b>	<b>0</b>	<b>0</b>	<b>11</b>	<b>0</b>	<b>10</b>	<b>0</b>	<b>27</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>61</b>	<b>0</b>	<b>60</b>	<b>0</b>	<b>6</b>	<b>0</b>	<b>11</b>	<b>0</b>	<b>8</b>	<b>0</b>	<b>24</b>	<b>0</b>	<b>220</b>	<b>0</b>
Other Pharmacologically Active Substances	B2f-National Plan	0	0	0	0	0	0	1	0	0	0	0	1	0	2	0	4	0	0	0	2	0	0	0	10	0	
	B2f- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B2f - Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B2f- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B2f- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>B2f- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10</b>	<b>0</b>	
Organochlorine Compounds including PCBs	B3a-National Plan	0	0	0	0	0	0	0	0	0	1	0	2	0	2	0	3	0	6	0	12	0	24	0	50	0	
	B3a- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B3a - Survey	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	0	
	B3a- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B3a- Imports	0	0	0	0	0	0	0	0	0	0	0	1	0	2	0	0	0	0	0	0	0	0	0	3	0	
	<b>B3a- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>6</b>	<b>0</b>	<b>12</b>	<b>0</b>	<b>24</b>	<b>0</b>	<b>55</b>	<b>0</b>
Organophosphorus Compounds	B3b-National Plan	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	3	0	4	0	3	0	12	0	
	B3b- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B3b - Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B3b- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B3b- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>B3b- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>12</b>	<b>0</b>	

Chemical Elements	B3c-National Plan	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0	2	0	6	0	2	0	9	0	22	0	
	B3c- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B3c - Survey	0	0	0	0	2	0	0	0	1	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	6	0
	B3c- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	B3c- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	<b>B3c- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>6</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>9</b>	<b>0</b>	<b>28</b>	<b>0</b>	
Mycotoxins	B3d-National Plan	0	0	0	0	0	0	1	0	2	0	1	0	1	0	3	0	4	0	1	0	4	0	3	0	20	0	
	B3d- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	B3d - Survey	0	0	0	0	1	0	0	0	0	0	0	0	3	0	4	0	1	0	0	0	0	0	2	0	11	0	
	B3d- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	B3d- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	<b>B3d- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>7</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>31</b>	<b>0</b>	
Dyes	B3e-National Plan	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	2	0		
	B3e- Suspect	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	B3e - Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	B3e- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	B3e- Imports	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	<b>B3e- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>		
Others	B3f-National Plan	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	8	0		
	B3f- Suspect	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0		
	B3f - Survey	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	B3f- Confirmatory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	B3f- Imports	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	1	0	0	0	0	0	3	0		
	<b>B3f- Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>8</b>	<b>0</b>	<b>0</b>	<b>13</b>	<b>0</b>			



## VETERINARY MEDICINES SECTION (VMS)

### Staff Composition for 2019

Period	Officers
January to November 2019	1 senior principal pharmacist 2 senior pharmacists 1 pharmacist
December 2019	1 senior principal pharmacist 2 senior pharmacists

### General Duties

The VMS section's general task is to ensure that the authorisation, manufacture, distribution, retail and use of Veterinary Medicine Products (VMPs) comply with EU Directive 2001/82 as well as Chapter 437 of the Laws of Malta and its Subsidiary Legislation (mainly S.L. 437.47 on VMPs and S.L. 437.73 on Medicated Feed). The section conducts inspections, registers VMPs and collects fees thereof and authorises/approves establishments dealing with VMPs, namely veterinary pharmacies, veterinary wholesale dealers, manufacturers and medicated feed traders/feed mills.

Other entities with which the VMS collaborated/co-operated with during 2019 include Malta Enterprise, Customs Department and Malta Medicines Authority.

### Participation in meetings/seminars/training

Officers participated in 21 events that were related with training abroad or meetings related with their line of work.

### Replies to Queries, Questionnaires and Surveys from EU or International Organisations

The section drafted 6 replies related with questions/queries/surveys originating from EU/International organisations. These were all cleared internally and through the relevant EU directorate at the Ministry.

The section also collaborated with its counterparts in the EU and assisted them in a number of investigations.

### Legislation Update of The Veterinary Services Act (Chapter 437) and Amendment of Veterinary Medicinal Products Regulations (S.L. 437.47)

The section continued assisting with the drafting of the Bill for the amendments of The Veterinary Services Act (Chapter 437 of the Laws of Malta) and also continued following the drafting of the Amendment to the Veterinary Medicinal Products Regulations (S.L. 437.47 of the Laws of Malta) through a Legal Notice. This involved a number of discussions with the State Advocate and Veterinary Surgeons Council (VSC).

### Simplification measures

The simplification measures with regard to online forms were implemented. Work started on the next stage of simplification with a new tool for online submission being driven by the Ministry's

CIO office. The section issued a guidelines document (also published on website) and a seminar was organised in July 2019 to explain to relevant parties the use of the new system.

## **Inspections**

In 2019, the section conducted 36 inspections as follows:

<b>Operator category</b>	<b>Number of Inspections</b>
Farms	6
Veterinary Pharmacy	11
Veterinary Wholesalers	13
Others	6

## **National Strategy and Action Plan Against Antimicrobial Resistance (AMR)**

Discussions continued with the Health Department in order to conclude the National Strategy and Action Plan Against Antimicrobial Resistance. In the meantime, a seminar was organised in October 2019 to explain important scientific aspects of AMR and ways how to reduce it to stakeholders. The VMS had a number of guest speakers for this event.

The section also actively participated in a wide-ranging consultative seminar on Antimicrobial Resistance with various stakeholders organised in January 2019.

## **Lectures delivered by the officers of the Veterinary Medicines Section**

In December 2019, officers of the Veterinary Medicines Section delivered a number of lectures to MCAST students regarding important scientific aspects of AMR and ways how to reduce it.

## **Vetting of Postal Parcels**

VMS continued vetting Postal Parcels received locally on a regular basis. The section withheld its 'no objection' for 7 postal parcels. Some parcels contained unidentifiable substances, others were illegal or did not follow the prudent use of antimicrobials. Some products were released with conditions.

## **European Surveillance of Veterinary Antimicrobial Consumption project (ESVAC)**

For the first time the section provided data on the sales of antimicrobials on the local market to the ESVAC by the European Medicines Agency (EMA). The data relates to the year 2017. The report was published on the EMA website.

## **Audits**

The sector was audited by the European Commission over the section's procedures with regard to inspection for Good Manufacturing Practice (GMP) and Batch recalls/Market surveillance. This is called the Joint Audit Programme (JAP) for EEA GMP inspectorates. A number of indicators were tackled and considered as fulfilled in 2019 such as those related with the preparation of SOPs and review of others. Other indicators highlighted by the auditors will be tackled in the short to medium term.

## **Online Veterinary Prescription**

The section kick started the process to introduce an on-line Veterinary Prescription. Intensive discussions started with CIO office. A consultation seminar was organised to explain to the relevant stakeholders (namely pharmacists and veterinary surgeons) the idea behind the project and get their suggestions (October 2019). A survey was launched to gauge the interest of each stakeholder and also obtain further information that could be useful.

## **Circulars Issued**

1 circular was issued by the section to local pharmacies on a counterfeit product for dogs (*Seresto collar*)

## **Endorsement of Import Licences**

The section endorsed 15 import licences and/or custom release papers to enable their subsequent release by Customs Department. An import licence was refused endorsement as it was for vaccines for which the presence of the disease was not confirmed.

## **Registration of Veterinary Medicinal Products and Generated Revenue**

During 2019, the section collected total revenue of €25,686. The section processed 550 applications which included applications for the first-time registration/authorisation of products or extensions thereof. The applications included post licensing procedures, such as withdrawals and variations.

## **Standard Operating Procedures (SOPs)**

All previous SOPs concerning the VMS were updated. A number of new SOPs were prepared. These were mainly those considered as lacking by the European Commission's JAP audit.

## **Part 2**

### **Overall compliance with feed and food law, animal health and animal welfare rules —**

#### **Section 9.2; Overall compliance by operators and products**

##### **9.2.1. Frequency and type of non-compliance**

VRD applies enforcement measures when it detects:

**1) Minor risk generic shortcomings;** these do not have impact on public and animal health, on the welfare of the animals. In the report of official controls these would be classified as **Observations/verbal requests**.

**2) Medium risk generic shortcomings.** These may be related to the attitude of the offender and may cause some risks impacting to public and animal health, on the welfare of the animals. In the report of official controls these would be classified as **Written Requests/Improvement notices**

**3) Specific shortcomings** that require specific intervention and failure to address them a specific risk to public and animal health, on the welfare of the animals is probable.. In the report of official controls these would require a **Corrective Action Request (C. A. R.)**.

**4) Offences to the Veterinary Services Act.** These offences may be repeated offences and will cause severe impact on public and animal health, on the welfare of the animals. These offences may also include assaults, resistance or wilful obstruction to an official veterinarian or any officer performing official controls in the exercise of his powers under the Veterinary Services Act is. First time offenders will be issued a **Warning Letter, unless the Director considers the offence severe enough for direct Court action.**

**5) Severe Offences to the Veterinary Services Act** that besides causing cause very severe impact on public and animal health, on the welfare of the animals may also imply fraudulent activities. For such offences administrative fines are foreseen. Offenders will be served the **Suspension of the License/Suspension of Approval** **Administrative fines are then issued in order to discourage such practices or the Director may have recourse to direct Court proceedings** **Certain legal penalties include imprisonment.**

### *9.2.2. Analysis of non-compliance*

Based on the reports gathered during 2019 when performing official controls in the food, feed and in the primary production sectors the most typical non-compliance actions tend to be:

1. Action against farmers for late notifications
2. Notices for improvement in HACCP implementation
3. Participated in action against farms
4. Notice for improvements in pharmacies and wholesaler - (Improvements were observed in the 2019 inspections)

#### **9.2.2.2. Nature of the risk arising from non-compliance**

Illegal keeping of unregistered animals has severe repercussions on human health . Court cases are therefore always initiated

Illegal slaughter and or meat cutting is also another non-compliance that may impact human health as these illegally slaughtered animals are not under official control. By carrying out slaughter in unauthorised premises, animal welfare is negatively impacted.

TheVRD, in collaboration with the Environmental Health Directorate has continued throughout 2019, to carry out several investigations and inspections. Often the investigations are aimed at controlling and repressing fraudolant activities; often such activities are carried out in registered premises and the VRD has offered its assistance to verify issues related to traceability

## **Part 3**

**Audits carried out as provided for in Article 4(6) of Regulation (EC) No 882/2004 including, where appropriate, the results of audits or inspections of control bodies as provided for in Article 5(3) of that Regulation — Section 9.3**

### **INTERNAL AUDITS**

Internal auditing is an independent and objective tool designed to add value and improve Competent Authority's operations. It helps the Competent Authority to reach its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of the activities, the risk management and the control and governance of the processes.

The audits are a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Within the Veterinary Regulation Directorate is operating an internal audit system developed and implemented in line with provisions of Article 4(6) of Regulation (EC) No 882/2004. Audits are implemented according to the instructions provided by the Food Safety Commission, a public entity which is legally required to carry out internal audits on the CAs in terms of Regulation (EC) 882 of 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. As indicated in the Internal Audit Manual of the Food Safety Commission, internal audits are carried out within the VRD as part of the series of internal audits carried out by the various Competent Authorities (CAs) making up the Food Safety Commission.

VRD has attempted to operate the internal audit system in line with provisions of Article 4(6) of Regulation (EC) No 882/2004. However, in 2019 the officer in charge of Internal Audits resigned, and, as a consequence, the programme was only partially completed. Although a Coordinator was subsequently appointed to organise the internal audits by other officers with the necessary expertise, this programme is still incomplete.

#### **External Audits ( NVL)**

In May, the NVL was audited on the In-house calibration activity of pipettes and balances by the National Accreditation Body (NAB). The outcome was satisfactory.

In June there was the annual NAB assessment which required review under the revised version of the ISO 17025 standard. The outcome was satisfactory and NVL is accredited under ISO 17025:2017.

#### **Internal Audits ( NVL)**

Internal audits are part of the ISO Standard and the NVL performs internal audits to cover the clauses of the ISO Standard and audits of the accredited test methods. Three types of audits were scheduled: witnessing, Horizontal and Vertical. The witnessing audits were performed on the following test methods: Salmonella, Trichinella, Sulphonamides, Antimicrobial residues and

antimicrobial resistance. There were 20 horizontal audits grouped into 4 audits and the vertical audit was on Trichinella.

All internal auditors have carried out Training on Internal audits

### **Risk assessment**

A risk assessment was carried out in order to prioritize the audits activity for the period from 2018 to 2020, according to threats and consequences for public health.

The hazards considered in the risk assessment are the different factors which can affect the appropriateness, efficiency and effectiveness of the controls. The possible presence of external unexpected threats which may influence the activity of the different VRD Units (e.g. emerging risk for animal health or food safety) were also taken into account.

Considering the difficulties for evaluating each threat in a quantitative manner, the risk assessment was carried out with a qualitative method.

The factors considered for the risk assessment are the following:

- Impact of the control activity for consumer interests and public health;
- Previous audit outcomes;
- Number of staff personnel;
- Economical weight of the FBOs controlled;
- Implementation of new control activities;
- Presence of emerging risks;
- Management of compensation mechanism;
- Strategic / Reputational / Political relevance of the control activity;
- Priorities defined in MANCP or EU programmes (FVO audits programme shall be considered);

The risk assessment and the programming of the internal audits are available on internet.

## **Part 4**

### **Actions to ensure effectiveness in operating the control plans, Section 9.4:**

Animal Welfare indicators: Podal Lesions

The Directorate had started monitoring at farm level, as well as during ante-mortem, podal lesions. Official veterinarians have monitored podal lesions at ante mortem as part of the department's key performance indicators. This program started in 2012 and become fully operation in 2013; it helps provide information to officials monitoring animal health and welfare at pigs' farm level.

When we look at the table, another decrease in number of animals affected is evident.

Furthermore, an important change was carried out in 2017 when the OV started deviding lesion into mild, medium and severe; in between brackets the number of severe lesions is indicated.

	2019	2019	2018	2018	2017	2017	2016	2016	2015	2015	2014	2014
			<u>Sows &amp; Boars</u>	<u>fatten ers</u>	<u>Sows &amp; Boars</u>	<u>Fattene rs</u>	<u>Sows &amp; Boars</u>	<u>Fatte ners</u>	<u>Sows &amp; Boars</u>	<u>Fattene rs</u>	<u>Sows &amp; Boars</u>	<u>Fattene rs</u>
Total lesions	11 sows	8 fatte ners	13	9	24	18	19	19	33	18	19	64
Number of affected farms					15(1)	12(3)	15	17	12	24	15	34
A% of farms					15.3	12.2	13.9	17.3	11.8	23.8	13,9	31,5

### **Animal Welfare Unit:**

This year the unit has issued 9 warning letters, and 4 prosecutions.

### **Animal Health Unit**

### **Animal Identification**

Non-Compliance with Regulation (EC) 1760/2000:

Holdings with non-compliance	5
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### **Sanctions imposed according with Commission Regulation (EC) 494/98**

According to the non compliances identified in the farms the following actions were adopted:

- 5 producers were given a warning letter or a final warning letter;
- all infringements were reported to the Paying Agency for further controls and deductions from the respective premia with regards to the Single Payment Scheme;
- 3 of the producers that were given a warning letters during the year now have no restriction on their herd;
- Total of 185 late notifications have been found and letters of late notifications have been sent to the corresponding farmers;

### **Findings of non-compliance**

Year	2019	2018	2017	2016	2015	2014
Number of non-compliant holdings	5	4	N/A	6	14	17

**Sanctions imposed in relation to Regulation (EC) 21/2004**

<b>Number of holdings with penalties imposed</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>Number of holdings with penalties imposed</b>	N/A	N/A	N/A	N/A	0	2
<b>Restriction of movements of all small ruminants on the holding</b>	14 (for a total of 217 animals)	6 (for a total of 318 animals)	N/A	138 animals on the 6 holdings with non-compliance	328	354 animals (on 17 holdings)

According to the non compliances identified in the farms, the following actions were adopted:

- 14 holdings with breaches were issued a warning letter or a final warning letter, as per internal SOP, Ref No: SOP/SFC/ 001/2011;
- all breaches were reported to the Paying Agency for further controls and deductions from the respective premia with regard to the Single Payment Scheme;
- 12 of the producers that were given a warning have settled their infringements during the year and now they have no restriction on the herd;
- 17 animals were confiscated and destroyed.



	Affected animals 2019	Affected holdings 2019	Affected animals 2018	Affected holdings 2018	Affected animals 2017	Affected holdings 2017	Affected animals 2015	Affected holdings 2015		Affected animals 2014	Affected holdings 2014
1. Restriction of movement of individual bovines	0	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
2. Restriction of movements of all bovines on the holding	599	5	291	4	N/A	N/A	0	0	60	1	
3. Destruction of animals	1	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	

### **Safety of the Food Chain Unit**

In 2019, 68 audits and 73 un/unannounced inspections were carried out on approved establishments. If shortcomings are detected during an audit there is a follow-up audit to establish whether the short-comings have been rectified. There were 25 follow-up audits in 2019.. The main issues encountered were structural maintenance of premises; the inability of the FBOs to interpret the Microbiological requirements as part of HACCP verification, and critical limits in HACCP plans that sometimes involved a range of values rather than one limit value. The latter issues are related to the difficulties in finding adequately-trained quality managers in micro-a and small businesses.

### **ABP Section:**

During 2019 one investigation on fallen ruminants was initiated.

### **Feeding Stuffs and Animal Nutrition Unit**

6 investigations have been carried out by this section

### **Trade Unit BIP**

A total 2,072.35 kg of products were seized, including both POAO brought by passengers at airport, and POAO found in parcels. Personal imports through MIA were 2,031.75 kg, while those through parcel post were 40.60 kg. All POAO seized were disposed for incineration.

## TRAINING

### Internal training

VRD personnel participated in several BTSF training courses and thereafter disseminated that training to other colleagues. This is included , with other training , in table below:-

	<b>Course Title</b>
1.	Bird of Prey Awareness workshop
2.	Prudent use of Antimicrobials in animals (AMR)
3.	Biosecurity Measures on Poultry, Swine and Ruminant farms
4.	Prevention and Control of Antimicrobial Resistance (AMR) in the context of an overall 'One Health' Approach to prevention and control of infections and reducing Antimicrobial Resistance
5.	Implementation of union rules in relation to microbiological criteria and on the monitoring and control of zoonosis and zoonotic agents.
6.	Auditing General Hygiene Requirements and Control Procedures based on the HACCP principles developed by food business operators
7.	Animal Welfare during Transportation Advance level.
8.	Putting Vaccination into Practice
9.	Training on Emergency Preparedness for transmissible animal diseases in the EU- ASF and AI
10.	Prevention and Control of Antimicrobial Resistance (AMR) in the context of an overall 'One Health' Approach to prevention and control of infections and reducing Antimicrobial Resistance-BTSF internal dissemination
11.	Prudent use of Antimicrobials in animals (AMR)-BTSF internal dissemination
12.	Refresher training for OV on emergency roster
13.	Animal Welfare during Transportation Advanced -BTSF internal dissemination
14.	Implementation of union rules in relation to microbiological criteria and on the monitoring and control of zoonosis and zoonotic agents-BTSF internal dissemination.
15.	HACCP Principles and Audit Techniques-BTSF internal dissemination
16.	Simulation exercise on the contamination of milk and feed with an Aflatoxin
17.	Control of commercial and non-commercial movements of dogs and cats-BTSF internal dissemination

18.	Training on the use of the Common Health Entry Document for animals (CHED-A) and products of animal origin, germinal products and animal by-products (CHED-P) in TRACES-NT-internal dissemination
19.	Food Hygiene at Primary Production” – PP Session 4 Land Animals-BTSF internal dissemination
20.	Milk Sampling and filling up of relevant documents
21.	Assisting the OV in red meat slaughterhouses
22.	Basic Procurement Procedures
23.	General inspections on farm
24.	International Bees Symposium
25.	ERA requirements training for OPM joint inspections on farms

### 3) NVL training:

A number of in-house training courses were carried out during 2019 for the laboratory officers covering certain general procedures like calibration of balances, micropipettes and also specific technical procedures for newly appointed personnel.

Specialised technical personnel from two EURLs came to the NVL premises to perform practical training of lab personnel. In September, an officer from the EURL for parasitology from the ISS of Rome, performed training on *Trichinella spiralis* detection. This session served as a re-training of NVL officers performing the analysis. In November, two technical officers from the EURL for Brucellosis in ANSES-France, performed a four-day training programme on Brucellosis analysis.

Another tailored-training session was organised by the EURL for antibiotics at Fougères-France for two NVL officers who went up to France in September for a 5-day training session which also included training on validation procedures.

### **External Training and Meetings**

The Veterinary Regulation Directorate continued to participate in various EU meetings and trainings on Veterinary related topics. A number of officials attended the meetings organised by the EU Commission, EU Council and other EU structures. Instructions notes including country positions were drawn up accordingly with respect to the topics of concern to Malta.

The Officers have attended on a regular basis to all the Better Training for Safer Food (BTSF) training sessions of the European Commission, monthly European Commission/Council meetings, Standing Committees, Working Groups/Parties, Workshops, other different meetings and conferences.

Officials have also attended trainings organised by the OIE, meetings and conferences organised by other entities such as the European Food Safety Authority (EFSA), Food and Agriculture Organisation (FAO) and DG SANCO Health and Consumers.

Staff of the National Veterinary Laboratory (NVL) have attended annual workshops on residue analysis organised by EU Reference Laboratories of different Member States in relation to NVL duties as the Maltese National Reference Laboratory.

Specialised technical personnel from two EURLs came to the NVL premises to perform practical training of lab personnel.

- In September, an officer from the EURL for parasitology from the ISS of Rome, performed training on *Trichinella spiralis* detection. This session served as a re-training of NVL officers performing the analysis.
- In November, two technical officers from the EURL for Brucellosis in ANSES-France, performed a four-day training programme on Brucellosis analysis.

Another tailored-training session was organised by the EURL for antibiotics at Fougères-France for two NVL officers who went up to France in September for a 5-day training session which also included training on validation procedures.

Officials of the Veterinary Medicinal section attended different meetings on various topics related to Veterinary Medicinal Products as per below table.

Month	Dates	Subject	Country	Officer
January	15-17	BTSF DG SANTE workshop on “ <i>Prudent use of Antimicrobials in animals (AMR)</i> ”.	Grange, Ireland	Ms. Elena Maria Vella
June	23-26	Assessors Training Course on Pharmacokinetic/Pharmacodynamic Modelling: Principles and Application in Veterinary Medicine.	Utrecht, The Netherlands	Ms. Nathalie Fenech
February	17-21	BTSF DG SANTE Training on “ <i>Prevention and Control of Antimicrobial Resistance (AMR) in the context of an overall ‘One Health’ Approach to prevention and control of infections and reducing Antimicrobial Resistance</i> ”.	Sofia, Bulgaria	Ms. Nathalie Fenech
September	02-05	Assessors Training Course on Pharmacokinetic/Pharmacodynamic Modelling: Principles and Application in Veterinary Medicine – Module 2	Utrecht, The Netherlands	Ms. Nathalie Fenech
March	13-15	QWP training-Learn to develop and draft regulatory documents on quality.	Prague, Czech Republic	Mr. Stephen Spiteri
June	26-28	Training Course on Quality Assessment of Veterinary Medicinal Products.	Berlin, Germany	Mr. Stephen Spiteri

## PROFICIENCY TESTING

As shown in Table 11 hereunder, the laboratory participated in a number of proficiency test (PT) schemes during the year 2019.

*Table 11 Proficiency Test Schemes*

NVL Section	Name of PT Scheme / Interlaboratory Comparison	Type of Analysis	Species and Matrix
Antibiotics Residues Screening	Progetto Trieste - Macrolides	ELISA	Bovine muscle/lyophilised bovine muscle
Antibiotics Residues Screening	Progetto Trieste - Beta Lactams	ELISA	Bovine Muscle
Antibiotics Residues Screening	Progetto Trieste - Quinolones & Fluoroquinolones	ELISA + SPT	Fish Muscle
Antibiotics Residues Screening	Progetto Trieste - Quinolones & Fluoroquinolones	ELISA	Turkey Muscle
Antibiotics Residues Screening	Progetto Trieste - Tetracyclines	ELISA + SPT	Hen Muscle
Antibiotics Residues Screening	Progetto Trieste - Macrolides	SPT	Poultry Egg
Chemical Analysis	Progetto Trieste – Sulphonamides	TLC	Turkey Muscle
Microbiology	Vetqas - Salmonella	Isolation	Animal Feed
Microbiology	Vetqas - Salmonella	Detection of Salmonella in Simulated carcass, chick box liner, faeces, boot swab	Poultry
Microbiology	Vetqas - Salmonella	Isolation	Animal Feed
EQAS for AST of E. coli	EURL – Denmark	Microbroth Dilution	Isolates of E. Coli
EQAS for AST of Salmonella spp	EURL – Denmark	Microbroth Dilution	Isolates of Salmonella spp.
AST	WHO - DTU Food	Microbroth Dilution	Salmonella/Campy
Parasitology	EURL Parasites - Trichinella Larvae	Digestive Method	Swine Muscle
Parasitology	EURL Parasites - Trichinella Larvae	Digestive Method	Swine muscle
Parasitology	EURL Parasites - Trichinella Larvae	Digestive Method	Equine muscle
Serology		ELISA	Serum

	FMD EURL - Anses France		
Serology	SVD EURL - Anses France	ELISA	Serum
Serology	Vetqas – Brucella	RBT	Serum
Serology	Vetqas - Bluetongue Virus	ELISA	Serum
Serology	EURL – Classical swine Fever	ELISA	Serum
Serology	Vetqas - Classic Swine Fever	ELISA	Serum
Serology	Vetqas – EBL	ELISA	Serum
Serology	Vetqas – Brucella	ELISA	Milk
Serology	Vetqas – EBL	ELISA	Milk
Serology	Vetqas - Brucella	ELISA	Serum
Serology	Vetqas - Brucella	Milk Ring Test	Milk
Serology	Vetqas - Brucella	RBT	Serum
Serology	Vetqas - EBL	ELISA	Serum

All but two of the PT had a satisfactory outcome.

Below in Table 12 are the details and corrective actions for those PTs that did not have a satisfactory outcome. These were reviewed during the ISO accreditation assessments and the outcome of the corrective actions were found to be compliant.

**Table 12 Proficiency Test Schemes**

<b>Test Method / Parameters</b>	<b>Name of PT Scheme</b>	<b>Results (+ve, -ve and Z-scores if applicable)</b>	<b>Result of Investigation (if -ve or close z score)</b>	<b>Corrective Actions Taken</b>
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<p>Detection of Trichinella Larvae – Swine Muscle</p>	<p>EURL Parasites</p>	<p>33 % Correct (Unsatisfactory)</p>	<p>False Negative</p>	<ul style="list-style-type: none"> <li>a) Contact the EURL regarding unsatisfactory PT participation;</li> <li>b) Request training material;</li> <li>c) Participation in further PT's (Oct &amp; Nov 2019);</li> <li>d) Requested additional training from EURL;</li> <li>e) Lab officers with unsatisfactory PT results not deemed competent to perform Trichinella analysis on their own until further training.</li> </ul>
<p>Detection of Salmonella in Simulated carcass, chick box liner, faeces, boot swab</p>	<p>VETQAS</p>	<p>4 out of 5 correct - 80% correct (Unsatisfactory)</p>	<p>False positive</p>	<ul style="list-style-type: none"> <li>1. Officer who had performed the PT and other personnel working within the section were repeatedly witnessed carrying out analysis - all process was satisfactory.</li> <li>2. A repeat PT sample was sent from VETQAS and result was satisfactory.</li> <li>3. Participation in larger number of Interlaboratory Comparison study for 2020.</li> </ul>

**ORGANISATION**

New Personnel:

NVL recruited 3 lab officers; within the Medicine Section, a pharmacist was recruited full time.

In 2019, VRD appointed new 3 support officers, another was promoted to a higher grade (Senior VO), and one was transferred.

## **Part 5**

### **Statement of Overall Performance, Section 9.5**

**The Directorate has set high level strategic objectives, in particular** to ensure that there is a comprehensive and integrated system of official controls from 'farm to fork' which contributes to protecting public and animal health and safeguarding consumer interests, to promote the welfare of animals and protect the interests of the wider economy environment and society by preventing, controlling and eradicating disease, and to encourage international trade.

The Directorate moved towards achieving these high level strategic objectives **by setting operational objectives**

#### **Strategic:**

- 1) Reduction of food borne illness by monitoring and reduction the incidence of *Salmonella* sp in Poultry flocks.**

Achievement of the targets:

The target was achieved in broiler flock (0.45%) and in the laying hens flocks (0%)

- Broiler Flocks**

This high strategic target has been met.

#### **Layer Flocks**

This high strategic target has been met.

In 2019, there were 26 flocks out of a total of 105 flocks infected with other serovars (24.7%) 25 were adult and 1 was rearing. Compared to 2018 there was a decrease in the prevalence of flocks infected with other *Salmonella* serovars going from 37.8% to 24.7%.

The serovars are listed below:

Serovar	No of isolates
Infantis	9
Haifa	3
Kentucky	7 (1 rearing)
Give	3
Croft	1
Livingstone	1

#### **Broiler flocks**

69 flocks were infected with other serovars.

Serovars	No of isolates
Infantis	9
Kentucky	22
Give	5
Haifa	22
Type V	1
Panamal	



Menden 1  
Gallinarum 1  
Livingstone 1  
Tomegbe 2  
Mbandaka 1  
Virchow 1  
Typhimurium 2

## 2) Prevention, Controls and disease eradication

Laboratory analyses of samples have been carried out according to the exigencies of the monitoring/control and eradication for a number of animal diseases as required by the Animal Health Unit. The reoccurrence of bovine **tuberculosis** in the Maltese island, which was first detected in 2017 with a second positivity in 2018, is a matter of concern as the last occurrence is dated back in 2001 and the country has obtained in 2016 the Tuberculosis official free status. The AHU has planned controls on farms for regaining the health status.

Farms were classified into high and low risk categories, depending on number of animal movements and history of having TB-reactors, or inconclusive reactors in the past. High risk farms are being tested every six months, and low risk farms every twelve months. Farms with TB-reactors are tested every two months until two consecutive whole-herd negative tests are obtained.

No new diseases have been detected. Due to the reduction in the number of positive results, the sampling protocol and testing frequency of the EBL programme has been revised since the vast majority of the bovine herds have now acquired the EBL-free status. Most farms are now being tested through bulk milk testing three times per year and by whole-herd serology using ELISA<sup>3</sup> once per year.

**This high strategic target has been partially met**

### Operational

1) During 2019, the checklists used for official controls that were digitised into “Self-assessment forms” for all FBOs falling within VRD remit, have been launched as an online system for some categories of approved establishments. ,

**The administrative objective target has been met for specific categories of approved establishments.**

### 2) To improve controls at border and in particular on transit and transshipments

A total of 1799 consignments of POAO were checked at the BIPs. Of those, 585 were inspected at MTMAR1 for internal market, 29 were inspected at MTMAR1 in transshipment to EU, and 1185 consignments in transshipment to third countries.

For all imported consignments a documental, identity and physical check was carried out in accordance to the requirements sets in the Council Directive 97/78.

**The administrative objective target has been met.**

### 4) Reduction of FBO non compliances

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<sup>3</sup> ELISA stands for enzyme-linked immunoassay. It is a commonly used laboratory test to detect antibodies in the blood.

In general and from the tables present in the dedicated section of the report it is evident that the number of enforcement actions have diminished. The efforts of providing good examples to the operators have given good results .

**The objective has been met.**

**5) To improve further collaboration with other competent authorities and especially with the Environmental Health Directorate.**

Joint inspections has been performed to prevent fraudulent or illegal activities including monitoring of illegally imported/traded food and feed. A number of enforcement actions have been carried out. A specific taskforce has been created within the Food Safety commission to prepare a food safety strategy that will also tackle memorandum of understanding to ensure all the Food Chain is under Official control.

**The objective has been met.**

**6) To improve the welfare of the animal on farm**

The emergency on farm system has worked on 24/7 basis throughout the year providing a very effective tool for the farmers who have managed to reduce distress to animals that in the past had to be put down on farm.

**The objective has been met**